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The Transnational Governance of Synthetic Biology

Scientific uncertainty, cross-borderness and the 'art' of governance

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Table of Contents

Executive Summary **3**

1. Introduction **5**

2.1 Conflicting narratives: New industrial revolution or old wine in new bottles? 6

2.2 Turning the debate back onto its feet 7

3. Identifying sources of concern **8**

3.1 Scientific uncertainty 8

3.2 Cross-borderness 9

4. Global development of synthetic biology **11**

4.1 The US: A lead in the initial industrialisation of research 11

4.2 The UK: Building research networks 11

4.3 China: The “Big Question” approach 12

4.4 A fuller picture of the global development of synthetic biology 13

5. Key Governance Challenges **15**

5.1 The salience of both knowledge and non-knowing 16

5.2 The cultivation of external accountability 17

5.3 Fragmentation of social authorities 20

5.4 Implications for international governance 21

6. The art of governance and governance as an art **23**

6.1 What is the subject of artistic governance? 23

6.2 What is the purpose of governance when performed as a form of art? 24

6.3 What may be better presented? 25

6.4 What should be left to network actors to ‘improvise’? 25

7. Concluding words **28**

References **30**

Annex I: Reports related to the governance of synthetic biology **35**

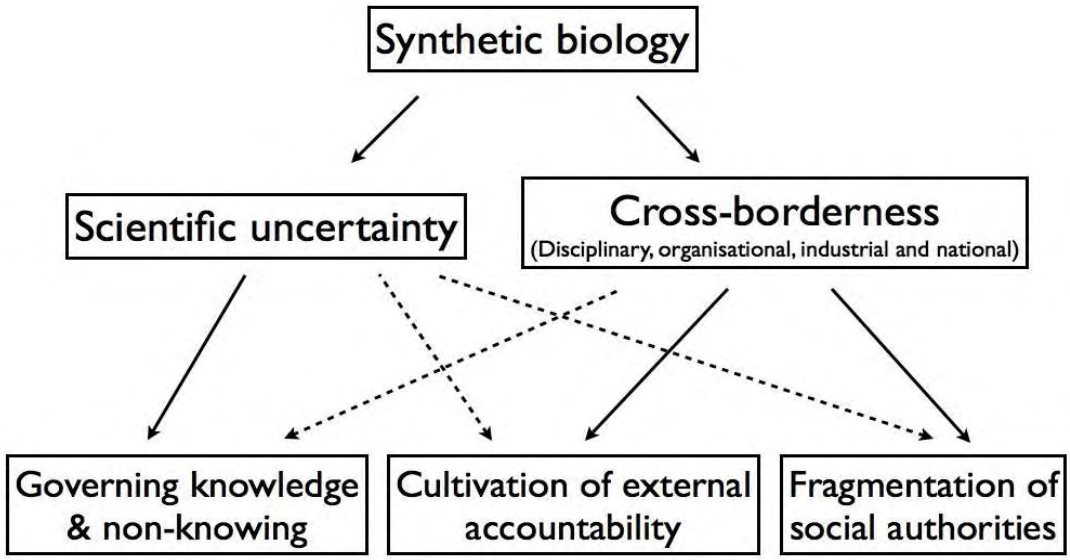
Executive Summary

Synthetic biology is a new field of research that aims to 'make biology easier to engineer'. Some claim that it could revolutionise biotechnology to deliver applications for the energy, medical and agricultural sectors. However there are concerns about potential environmental and health risks, the creation of monopolies dominated by large multinational corporations, and the ethics of creating artificial life. How should synthetic biology be best governed to maximise benefits and minimise risks? In the last seven years, some 40 reports (in the English language alone) have addressed the social, ethical and legal issues raised by synthetic biology. This Working Paper, based on an extensive literature review and fieldwork in the UK, China and Japan, BIOS proposes a radical new approach to these issues.

- The paper goes beyond proposals to mitigate specific risks of synthetic biology to investigate the root causes of such concerns, and address the challenges at an overarching level.
    - We argue that effective governance regimes must address two central features of synthetic biology: scientific uncertainty and cross-borderness.
    - By uncertainty we point to the fact that many future implications of synthetic biology, like other emerging biotechnologies, are not only difficult to predict but are fundamentally unknowable.
    - By cross-borderness, we point both to inter-relations between geopolitical regions, and to the growing interconnectedness across academic disciplines and industrial sectors.

- We argue that effective governance in the face of scientific uncertainty and cross-borderness is best framed, not as a rigid regulatory regime, but as a flexible and evolving ‘art of governance’. Effective governance seeks to foster good science, not to hamper it, but recognises that good science goes hand in hand with open, clear, transparent regulation to ensure both trust and accountability.

- Such an ‘art of governance’ seeks to facilitate effective interactions between the range of current and emerging social actors involved in or affected by scientific and technological developments, to ensure that all parties have the opportunity to express their perspectives and interests at all stages in the pathways of research and development, through transparent and democratic processes. The art of governance recognises that no decisions will suit all actors, but effective compromise depends on ensuring openness and transparency in the process by which decisions are reached, demonstrating genuine consideration of all perspectives.



We highlight three crucial challenges for the effective national and international governance of synthetic biology:

- FIRST, governance of science is not just a matter of governing the production and application of knowledge, but must also recognise that scientific uncertainty is not merely temporary but endemic: not merely calculable risks, but provisional unknowns, unknown unknowns, and even wilful ignorance or a conscious inability-to-know. Such 'non-knowing' cannot be overcome simply by acquiring more knowledge: increasing knowledge often leads to increasing uncertainty. Effective governance of synthetic biology must give explicit and attention to both knowledge and non-knowing.

- SECOND, synthetic biology relies on collaborative contributions from distinct disciplines and professions, and this requires accountability beyond that internal to each field. While good governance of synthetic biology demands proper accountability within scientific disciplines and professional bodies, it also requires the cultivation of external accountability, not only across and between such fields, but beyond, to all those who may be affected. Such networks of accountability accommodate change over time, facilitate mutual trust and responsiveness among various groups and constituencies, encourage good practice and robust science, and enhance openness and transparency.

- THIRD, the combination of scientific uncertainty and cross-borderness ensures that no single group, organization, constituency or regulatory body will have the capacity to oversee, let alone to control, the development of synthetic biology. An art of governance is required to accept the constitutive fragmentation of social authorities, and to work with such diversity, not as a hindrance, but as a condition of, and advantage for, effective governance.

In the light of these three challenges, we argue that scientifically informed, evidence-based approaches to policy-making, while essential, are insufficient. It is time to bring back a sense of the ‘art’ to the governance of biotechnology: an approach which employs proactive, open-ended regulatory styles able to work with uncertainty and change, to make links across borders, and to adapt to evolving relations among changing stakeholders, including researchers, research funders, industry, and multiple publics.

1. Introduction[1]

This working paper summarises and appraises current thinking and proposals for the governance of synthetic biology. Considering that contemporary synthetic biology was only born around 2004, when the first international conference (SB1.0) was held, the extent of the literature already produced about the governance of this field is very extensive. Annex I lists 39 reports produced since 2004 by scientific, governmental and non-governmental organisations, and shows how activity in this field has increased rapidly in the last few years, with 28 reports published in just the last 3 years. Alongside this grey literature, there are also numerous articles published in academic journals by synthetic biologists, sociologists, legal scholars and philosophers. We have utilised this literature as a resource and particular attention has been paid to identifying the range of views expressed by different actors. This literature review is complemented by participant observation in synthetic biology laboratories, scientific meetings and policy forums in the UK, as members of the joint LSE-Imperial College Centre for Synthetic Biology and Innovation (CSynBI). Additional fieldwork consisting of laboratory visits and interviews with scientists and policy makers was conducted in the UK (by Claire Marris), in China (by Joy Zhang) and in Japan (by Caitlin Cockerton and Susanna Finlay).

The report is organised as follows:

- Section 2 summarises current accounts of synthetic biology and explains how conflicting narratives occur in parallel.
- Sections 3 and 4 then elucidate the main sources of governance challenges exhibited by synthetic biology. Section 3 demonstrates that current concerns over synthetic biology mostly originate from two key features of synthetic biology: scientific uncertainty and cross-borderness. By examining the case of the US, the UK, China, Section 4 further illustrates both the inter-national divergences and the transnational interconnectedness that any governing attempts for synthetic biology need to take into consideration.
- Section 5 discusses three key governance challenges that arise from these two features of synthetic biology: the salience of both knowing and non-knowing; the need for external accountability; and the fragmentation of social authorities.
- Section 6 outlines our proposal for the 'art of governance' to address these challenges.

[1] We would like to thank Dr Jane Calvert, Prof. Robert Falkner and Prof. Andy Stirling for their useful comments on an earlier draft of this paper.

2. Current accounts of synthetic biology: conflicting narratives

In this section, we summarise current accounts of synthetic biology found in existing reports.

2.1 Conflicting narratives: New industrial revolution or old wine in new bottles?

Existing discussions on synthetic biology often depict two different stories. On the one hand, synthetic biology is portrayed as the force for a "new industrial revolution" (RAEng, 2009) delivering an "unrivalled set of technological 'solutions'" (NEST, 2005). With economic promise in a wide range of different sectors including the development of renewable energy, biosensors, sustainable chemical industries, microbial and plant drug factories and biomedical devices, synthetic biology appears to be at the convergence of diverse investment interests, with some consultancy firms forecasting a market of over $3.5Billion in the next 10 years (Beachhead Consulting, 2006). Yet on the other hand, apart from initiatives from a few corporate oil giants, current market prospects for synthetic biology look rather bleak, as pharmaceutical and biotechnology companies "do not seem to play a significant role in synthetic biology development" (de Vriend 2006: 41). This reluctance over supporting synthetic biology is often attributed to the long-term nature of the translation research process (House of Commons 2010: 15-17) and the need for public funding to develop "foundational tools". The Royal Society of Edinburgh highlighted that there was "no real substitute" for government in terms of sponsorship (Royal Society of Edinburgh, in House of Commons 2010: Ev129).

Alongside such inconsistent assessments of synthetic biology's economic significance, there are also two conflicting stances on regulatory frameworks. On one hand, many interested parties advocate that a traditional top-down governmental administration should give way to a bottom-up multi-participant governance approach. It is emphasised that "partnership with civil society groups, social scientists and ethicists should be pursued as a highly effective way of understanding critical issues" concerning synthetic biology, which may in turn contribute to more pertinent regulatory schemes (Balmer and Martin, 2008). On the other hand, amidst these propositions, most recommendations indicate a strong expectation for government to play a central role in synthetic biology regulation. In other words, despite a shared support for encouraging what political scientists describe as "a pluricentric form of governance in which decision making involves a plurality of actors, arenas and processes" (Sorensen and Torfing, 2009: 255, emphasis added), the role of the government still dominates current regulatory discussions.

More fundamentally, there are opposing views on the novelty of the field and the perceived novelty of risks of synthetic biology. Some have argued that synthetic biology "clearly represents a scientific paradigm shift" (Kelle, 2007: 4). If synthetic biology delivers its promise to "make biology easier to engineer", producing standardised biological parts that can be assembled in a modular fashion to produce predictable and robust functions designed using computers, and if these biological parts are made publicly available, then the danger of unlicensed individuals synthesizing lethal viral genomes is portrayed as being imminent (Bio-ERA, 2007). We are repeatedly warned that "We can expect huge benefits [from synthetic biology], but - as with any critical advancement in science - there are also risks. It is important to address ethical and safety concerns, and to address potential or perceived risks of synthetic biology from the very beginning, so that future developments can be fostered and established with the support of the public at large." (NEST, 2005, p. 3). Meanwhile, it is also argued that "the basic techniques necessary for conducting some form of synthetic biology already exist and are publicly accessible. Thus, many of the risk of potential abuses exist already" (NEST, 2005: 18-19). For example, the SB2.0 conference has highlighted the view that: "the vast majority of today's biosafety and biosecurity concerns predate synthetic biology and would be substantially the same even if this new field did not exist" (Maurer et al., 2006: 2). As Benner and Sismour (2005) put it, "placing a new name on an old technology does not create a new hazard".

2.2 Turning the debate back onto its feet

To summarise, when analysing the implications of synthetic biology, actors sometimes underline its novelty, and highlight the unprecedented industrial and governance challenges it poses; or conversely downplay it as old wine in a new bottle. There is no simple correlation between the nature of social groups (such as regulatory institutions, scientific community, NGOs, companies etc.) and their pronouncements about synthetic biology. In fact, views on whether synthetic biology should follow previous experience or be treated differently often vary even within the same report, depending on which topic (such as financial, ethical or environmental implications) is under discussion. In short, existing debates have demonstrated that synthetic biology - like any new field of science and technology - can be portrayed equally as in continuity with, or radically distinct from, previous biotechnologies; and this can occur within the same perspective, depending on the context of the discussion

Thus, we are sometimes warned that "evolving synthetic biology research pose[s] a fundamental challenge to the current regulatory structure" (OECD & the Royal Society, 2010: 35; NEST, 2005; Parens et al., 2009), yet at the same time these challenges are thought to be met by borrowing national and international regulatory patchworks from GMOs, stem cells, chemicals, cosmetics, biotechnologies, data protection and risk management (EGE, 2009: 27-31) and many conclude that "Overall, the existing regulatory framework is working well" (RAEng, 2009: 48). While the novelty and revolutionary nature of synthetic biology is emphasised in some contexts, and seems to imply that something be done, when examination of the regulatory agenda becomes more specific there always seem to be arguments that nothing else need be added.

One contributory factor to this regulatory paradox is that many existing reports overlook the 'trans-scientific' nature of emerging technologies, and how the construction of governance response should be "profoundly and legitimately political and cultural as well as technical and economic" (RCEP, 2008: 58). Instead, many tend to frame the problems posed by synthetic biology in a way that matches established policy categories. As a result, the governance of this area has to some extent become an act of 'filling the prescription', or formatting the problem to fit readily available solutions. Moreover, the same format is often used to address these questions. We find for example that many reports, such as the reports produced by the Royal Academy of Engineering (RAEng, 2009), the European Group on Ethics in Science and New Technology (EGE, 2009) and the Rathenau Institute (de Vriend, 2006), follow the same structure. They all start with introducing the technical aspects of synthetic biology development, then follow with discussion on specific regulatory issues (such as biosecurity, biosafety, IP), then move onto less tangible issues, i.e. "ethical and social implications", and finally conclude with an open-ended call for public involvement. This sequence from technical facts, scientific evidence, to ethical/social concerns and public engagement conforms to the prevailing view that governance first needs to be based on scientifically sound evidence, and that ethical/social concerns can be separated out and addressed 'downstream' from innovation processes.

This paper attempts to turn the debate about the governance of synthetic biology from its head back to its feet. Rather than compiling an exhaustive list of issues that match ready-established policy categories (or providing another 'bottle' to frame research activities), it focuses on comprehending the current dynamics of synthetic biology. It elucidates the technical and social context which enables the paradoxical views to co-exist, and uses this as a basis to explore essential governance concerns and possible solutions. Effective governance seeks to foster good science, not to hamper it, but recognises that good science goes hand in hand with open, clear, transparent regulation to ensure both trust and accountability.

3. Identifying sources of concern

By incorporating current scientific, social, economic, legal and political dynamics of the field, our research identifies two fundamental dynamics within synthetic biology that any attempt for the governance of synthetic biology inevitably confronts: (i) scientific uncertainty, which needs to be understood more broadly than 'risk' and (ii) cross-borderness, which not only entails inter-disciplinarity between scientific and engineering disciplines, but also necessitates multi-lateral collaborations among various kinds social actors (scientific and non-scientific) in different geopolitical regions. Neither of these two features is entirely new or unique to synthetic biology: many modern sciences have also, to varying degrees, exhibited features of scientific uncertainty and cross-borderness at multiple levels (disciplinary, organisational, industrial and national). Synthetic biology, because it explicitly aims to create such synergies, seems to have intensified and dramatized some of the key challenges confronted by modern scientific governance. The conflicting accounts of synthetic biology described in the previous section are, according to our analysis, social reactions to these two fundamental features.

3.1 Scientific uncertainty

It has long been recognised that along with their expansion of social choices and developmental promises, modern scientific inquiries have also produced a social consciousness among stakeholders about the inadequacy, imperfection and fallibility of scientific knowledge (Beck, 1992).

According to the International Risk Governance Council, synthetic biology can be seen as a source of emerging risks (IRGC, 2010). This is to say, it is a scientific practice whose consequences can be "perceived to be potentially significant but which may not be fully understood and assessed, thus not allowing risk management options to be developed with confidence" (IRGC, 2010: 6). For example, one issue which is recognised as potentially problematic in existing approaches for risk assessment of GMOs when applied to synthetic biology is that they are largely based on comparison between the new engineered organism and its natural counterpart and focus on the attributes of the recipient/parental organism, donor organism and vector used to transfer the DNA. But if individual genetic components or whole genomes are able to be designed using a computer and then chemically synthesised, concepts of "recipient" and "donor" organisms may lose their significance. Moreover, synthetic biology studies are not limited to the modification of natural organisms, but also extend scientific practice to the construction of new life forms. "Certain products, such as minimal cells, for which there are no natural comparators, may present new challenges in characterizing risk" (BBSRC, 2008a). In these discussions, however, it is important to remember that "even if the source of all of the parts of a synthetic microorganism are known, and every new genetic circuit understood, it would be difficult to predict in advance whether the organism would have any unexpected emergent properties." (Rodemeyer, 2009: 27). As we shall see in section 5.1, these are the kinds of unknowns which are often overlooked in policy when it is over-determined by scientifically informed bureaucracy.

In its 2009 proposal for new biological risk assessment, the Royal Society has divided the "risk spectrum" into three main areas: naturally occurring risk (e.g. disease), unintended risk (e.g. the dual use of research findings) and deliberate weaponisation of biological agents (Royal Society Science Policy Centre, 2009). All of these potentially apply to synthetic biology and several reports have noted that concerns over synthetic biology are not just about "bioterror", or the intentional abuse of scientific power by malevolent individuals or institutions, but also about "bioerror" (ETC, 2007; Lloyd's Emerging Risks Team, 2009; RAEng, 2009). These two terms are sometimes used simply to distinguish between security and safety risks, but some actors use "bio-error" to emphasise what they see as unforeseen unintended harmful environmental or health consequences of the technology developed by legitimate scientific researchers working in state-sanctioned institutions. This sense of "bioerror" calls into question existing institutional estimation of technical control and conventional assessments on the validity of 'evidences'.

Acknowledgement of scientific uncertainty is not only based on the recognition of the fallibility and partiality of knowledge, but also based on an acute awareness of non-knowing (Beck, 2007 [2009]:115-128), such as provisional unknowns, unknown unknowns, wilful ignorance and the

conscious inability-to-know. Governance of science is not just a matter of governing the production of knowledge, the application of knowledge or the future expansion of knowledge. Rather, governance of science is equally a matter of regulating the implications of uncertainty, ignorance and indeterminacy (Stirling, 2008 and 2010; Wynne, 1992). The subsequent governance challenge posed by the salience of both knowledge and non-knowing is further discussed in Section 5.1.

3.2 Cross-borderness

In addition to embedded scientific uncertainty, a prominent feature of synthetic biology is its 'cross-borderness'. To fully comprehend the dynamics of synthetic biology, it is necessary to understand how it simultaneously crosses the borders of (a) scientific disciplines, (b) industrial sectors, and (c) geopolitical areas.

Through the application of engineering principles to the design, control and construction of living systems, synthetic biology seeks to integrate a number of research disciplines. Some immediate examples include computational science, engineering, information technology, biology, chemistry and nanotechnology. The European Commission programme, New and Emerging Science and Technology, concluded that "the major challenge" of synthetic biology was "the synthetic integration of existing disciplines" (NEST, 2005: 10). In the UK, funding initiatives for synthetic biology stress the need to foster the building of a new "cohesive, cross-disciplinary community" and aim to "overcome research language barrier" (BBSRC, 2007). Thus, synthetic biology is often characterised as an emerging "hybrid discipline" which will combine "elements of both engineering and science to achieve its goal of engineering synthetic organisms" (Adrianantoandro et al., 2006:12).

It is however important to acknowledge that synthetic biology does not merely 'transcend', or 'go beyond' existing disciplinary borders and establish research norms that are completely new, and that forming innovative inter- or multi-disciplinary partnerships involves more than overcoming language barriers. Different scientific disciplines have very different "epistemic cultures" (Knorr-Cetina, 1999): different understandings about what knowledge consists of, how it is produced, and how to utilise it. This is particularly true of biology and engineering and attempts to combine them (which precede contemporary synthetic biology) can lead to difficulties (Fox-Keller, 2002).

Despite efforts in cultivating a first generation of synthetic biologists through newly-introduced post-graduate courses, at least in the near future, synthetic biology may still rely on the contribution from already established "parent disciplines". In fact, a practicality pointed out by Royal Academy of Engineering (2009: 49) is that taking into account the amount of expertise needed, future synthetic biologists will be required to be trained "in a core discipline before moving into interdisciplinary research". Thus many researchers may still feel committed to "parent disciplines" from which researchers "derive their primary peer support and recognition" (RAEng, 2009: 49).

In other words, from a governance point of view, it is more prudent to recognise potential difficulties synthetic biology may encounter in operating and communicating across different scientific fields, rather than assuming it will easily unify all branches into one. This is the first type of cross-borderness that this paper identifies as a crucial challenge for governance. Such inter-disciplinary cross-borderness has important consequences. For example, Drew Endy, a leading synthetic biologist at Stanford University, has pointed out that a pertinent question in meeting biosafety and biosecurity challenges is how identified risks can be communicated and understood across disciplinary boundaries:

> "…the majority of people coming into synthetic biology aren't biologists. They're physicists or computer scientists or electrical engineers and so they're just of a different culture. They don't have a lot of experience with microbiological safety. So you need to gain access or transmit knowledge across not just a generational gap, but across cultural divides".
> (Endy in Lentzos et al., 2009: 319)

For scientists in the field, such as Drew Endy, the view is not so much that synthetic biology has easily overcome disciplinary differences, but rather that practitioners have to work with these differences on a day-to-day level. Access to other fields cannot be taken for granted but has to be 'gained' while knowledge has to be explained, communicated or translated "across not just a generational gap, but across cultural divides".

Discussions about intellectual property (IP) regimes for synthetic biology also highlight difficulties arising from its position "at the confluence of biotechnology and computing" (Rai and Boyle, 2007: 58). Software "neither fit[s] into the intellectual property regime of patents or copyrights; an issue that [is] hardly resolved by forcing it under both" (Balmer and Martin, 2008:23). One highly visible and influential group of synthetic biologists seeks to promote an open source culture, modelled on development in computer software, through the Registry of Standard Biological Parts, iGEM, the BioBrick Foundation and its BioBrick Public Agreement (BPA). However, at a recent workshop on Open Source held at the LSE, social science scholars and synthetic biologists broadly agreed that research practice in synthetic biology did not (or at least not yet) represent such a radical shift in normative cultures and pointed out that research infrastructures such as the MIT Registry and the BPA allowed for traditional patenting of biological parts. Thus future synthetic devices are likely to incorporate both unpatented and patented parts from different industrial sectors.

IP discussions also illustrate two other types of 'cross-borderness' that can give rise to difficulties for regulators. Firstly, at an industrial level, "a clash of cultures is likely to become an issue. A pharmaceutical company, a chemical industry, a university or a semiconductor company all see intellectual property rights differently and it is difficult to align their interests" (OECD & the Royal Society, 2010: 41). Secondly, at an international level, although the basic rules relating to patents are almost universal, the patents themselves are national or regional and it is at the inventor's discretion to choose the jurisdiction in which protection is sought. Thus, the complexities and resulting uncertainties over the patentability of synthetic biology and the unsettling disputes among industries are of importance not only to domestic scientific advancement but also to transnational compatibility and competitiveness.

Under the banner of synthetic biology, industries that may have been previously categorised as subject to different regulatory agencies, following different priorities and supervised by different sets of rules, may now need to be summoned to the same policy round-table. In addition, the possibility of "garage biology", with individuals purchasing DNA sequencing equipment from eBay and conducting synthetic biology at home, challenges the boundary between private pastime and public liability. As noted by the OECD and the Royal Society in their recent joint workshop report (2010: 41), "synthetic biology is being developed both within and outside of the traditional arenas of science and technology R&D".

These examples demonstrate how synthetic biology should be seen as multi-lateral interdisciplinary research. It is interdisciplinary because it seeks the collaboration of expertise among previously specialised lines of research. It is multi-lateral because it interconnects different aspects of social and economic practice and calls for consortiums of diverse relevant social actors in resolving related problems. As will be pointed out in Section 5, such cross-borderness a) signifies the importance of establishing accountability with actors outside one's parent discipline or social sector; and b) contributes to the fragmentation of authorities. The 'cross-borderness' of synthetic biology should also be comprehended in the more traditional sense as scientific research that crosses national borders and geographic distance. This point is developed in the next section.

4. Global development of synthetic biology

Synthetic biology is being simultaneously developed in different parts of the world. Subsequently, the progress of synthetic biology is subject to different political regimes that are interwoven with each country's historically developed R&D system and scientific traditions.

To elucidate the possible regulatory divergences among nations, this section compares the development trajectories exhibited in three major nation-state players: the US, the UK and China. The comparison is based on data from existing reports and fieldwork in the UK and China. It is worth emphasising that it is beyond the ability and interest of this paper to produce an all-encompassing summary of the practice of synthetic biology in these countries. The comparison below focuses only on major funding sources, emerging national research strategies, and key regulatory concerns in each country. It is not aimed to be comprehensive. The intention here is to demonstrate the regulatory diversity that governance endeavours may need to be attentive to. In addition to an inter-national examination, a fuller picture of the global development of synthetic biology is further investigated in Section 4.4 by examining the importance of trans-national initiatives that transcend nation-state categorisations.

4.1 The US: A lead in the initial industrialisation of research

Compared to many countries in which synthetic biology research is still in its infancy, this field is often described as "already established" in the US (POST, 2008: 2). America plays a dominant role in scientific publications, research personnel training and funding sources (from both public and private sectors), and is also at the forefront of the initial industrialisation of synthetic biology.

The Woodrow Wilson Center has identified 184 synthetic biology-related institutions in the US, and 80% of these sites are universities and companies (Woodrow Wilson Center, 2010). Venture capital and philanthropic foundations such as the Bill & Melinda Gates Foundation are funding pharmaceutical applications, such as the malaria drug, artemisinin. Small specialised companies such as LS9, Amyris, OPX Biotechnologies, Solazyme, Gevo and Synthetic Genomics are working towards the commercialisation of biofuels (Rodemeyer, 2009: 18-20). Government funding also reflects a sense of industrial interests. According to the Woodrow Wilson Center (2010), since 2005, the U.S. government has spent approximately $430 million on research related to synthetic biology, with the Department of Energy (DOE) funding a majority of this research. Other national funding institutions are the National Institutes of Health, the National Science Foundation and the Department of Agriculture.

4% of US government funding for synthetic biology has been allocated to examine the ethical, legal and social implications of synthetic biology (Woodrow Wilson Center, 2010: 2), with an emphasis on biosecurity. So far, the US governmental policy agency, the National Science Advisory Board for Biosecurity (NSABB) has issued two guidelines addressing dual-use issues of synthetic biology (NSABB, 2006 and 2010). One novel dimension at SynBERC, one of the major research centres, has been the participation of social and human scientists in the "Human Practices" thrust (Rabinow and Bennett, 2009).

4.2 The UK: Building research networks

In contrast to the US, despite the founding of "a number of very small companies", the UK has not yet shown "any significant industrial activity in synthetic biology" (Kitney in House of Commons, 2010: Ev22). In 2008, the UK had "only one commercial DNA synthesis company compared with 24 in the US" (POST, 2008: 3), and in 2010 the House of Commons Science and Technology Committee concluded that "while research is well funded there is not enough forethought about synthetic biology translation, for example developing DNA synthesis capability, which would provide the UK with an excellent opportunity to get ahead internationally. If this is not addressed, synthetic biology runs the

risk of becoming yet another story of the UK failing to capitalise on a strong research base and falling behind internationally" (House of Commons, 2010:3).

According to a report by the Woodrow Wilson Center, since 2005, the estimated funding of synthetic biology in the UK was between $30 million and $53 million (Woodrow Wilson Center 2010: 8), divided between government research councils and medical charities (such as the Wellcome Trust). When giving evidence to the House of Lords select committee on S&T, the UK Research Councils stated they had spent around £20 million on synthetic biology in 2007-08.

The first funding initiative that specifically targeted synthetic biology was the "Networks of synthetic biology" initiative, jointly funded in 2008 by four UK research councils: Engineering and Physical Sciences Research Council (EPSRC), Biotechnology and Biological Sciences Research Council (BBSRC), Economic and Social Research council (ESRC) and Arts and Humanities Research Council (AHRC). The rather modest sum of £891k was allocated to the setting up of seven UK Networks. Each of these is led by a separate university with different research agendas. The aim of these Networks is to encourage "interdisciplinary and multidisciplinary partnerships" and to "build a cohesive, cross-disciplinary community in synthetic biology". In 2009, the EPSRC awarded a Science and Innovation award of £5 million to Imperial College, in partnership with the London School of Economics, to create the Centre for Synthetic Biology and Innovation (CSynBI). These awards aim to "build new activity in areas of national strategic importance".

The UK has been particularly prolific in the production of grey literature on synthetic biology, with at least 11 reports published by UK organisations in the last 4 years (see Annex I for details). Another related feature of UK synthetic biology is the heavy enrolment of social scientists: about 40 are associated with the Networks, and the LSE is a partner in CSynBI. The role of these researchers is not entirely clear, but there is a sense that their participation should ensure that "the societal issues are considered from the start" (BBSRC, 2008b).

4.3 China: The "Big Question" approach

Synthetic biology research remains in its infancy in China, with few nationally funded projects and no identified industrial involvement (Yang, 2010). Funding remains scarce and mainly restricted to national funding agencies such as the National Natural Science Foundation of China and the Ministry of Science and Technology (MOST). Synthetic biology was listed as a priority area in MOST's funding scheme for the first time in 2010, although no successful applications were awarded (MOST, 2010).

To some extent, it could be argued that China's involvement in synthetic biology was largely promoted by students' participation in the iGEM competition (Zhang, 2008). China's initial appearance in iGEM was in 2007 with four teams, whose training and research activities were mainly concentrated in the Beijing-Tianjin region. In the 2010 competition, there were eleven teams from nine universities dispersed in six Chinese mainland provinces or municipalities. In parallel to the development of iGEM participation, the Beijing-Tianjin region, Anhui Province and the city of Shanghai have, to different degrees, all initiated synthetic biology research programs. Most synthetic biology-related research initiatives are either led by universities or by Chinese Academy of Science (CAS) affiliated research institutions.

Our fieldwork in China found that a "Big Question" approach has been under discussion in China's synthetic biology community (Zhang, 2011). This proposed national strategy is often compared with China's earlier collaborative efforts for the synthesis of crystallized bovine insulin in 1965. It is aimed at organizing dispersed national expertise into the same project, which is founded on one "Big Question" that is essential to the technical development of this field. Deriving from this foundational question are a number of supporting fields of research and more specific research topics. These sub-themes and sub-topics are then designated to individual universities and research institutions. Such an approach is intended to create nation-wide synergies with the spirit of working towards the same key research question. It is also believed by scientists interviewed that such a top-down nation-wide organization may provide incentives and sustained financial backing for the production of

intermediary results. Currently such a proposition is still at a consultation stage, supervised by the MOST.

In China, public debate regarding synthetic biology still remains minimal and most media reports have been positive (Pan, 2008; Huang, 2009; Fang and He, 2010), but it seems that the Chinese scientific community is learning from past lessons of life science development, in which inattentiveness to global ethical concerns have linked China with the image of "the 'Wild East' of biology" (Dennis, 2002) – a view that many within China consider fails to recognise the strides that have been made in developing laws, regulations and guidelines to govern research and practice in many areas of biotechnology, notably those related to biomedicine[2]. Despite the fact that most synthetic biology-related research is only at a preliminary stage, a national conference on the ethical and biosafety issues concerning synthetic biology was jointly hosted by China Association for Science and Technology, Chinese Society of Biotechnology and Beijing Institutes of Life Science CAS, in Suzhou June 2010 (BILS, 2010).

4.4 A fuller picture of the global development of synthetic biology

These brief overviews of the way synthetic biology has been developed in three different nation states provide us with some examples of divergences that stakeholders can expect to come across, but such a mosaic display of research contexts illustrates only part of the global picture. A fuller picture is provided when transnational activities are also included in the analysis, because the development of synthetic biology in many countries has been closely associated with transnational endeavours.

The globalization of synthetic biology research is catalyzed by transnational funding programmes. The first synthetic biology project in China was not funded by Chinese sources, but was part of the "Programmable Bacteria Catalyzing Research (PROBACTYS)" funded under the European Commission's Sixth Framework Programe (Yang, 2010). In 2009 the US NSF and UK EPSRC jointly funded a "sandpit" at which five research projects involving joint US-UK teams were developed and awarded funding. Within Europe funding of international projects has come via the European Commission's New and Emerging Science and Technology (NEST) Sixth Framework Programme (FP6) and the European Science Foundation's EuroSYNBIO programme.

Transnational developments are also visible in several governance initiatives, such as the workshop organised jointly by the OECD, the US National Science Foundation and the UK Royal Society in 2009, a joint project between the Austrian Science Fund (FWF) and the National Natural Science Foundation of China (NSFC) on "Investigating the biosafety and risk assessment needs of synthetic biology in Austria and China", and an ongoing project which brings together the 6 science and engineering academies from the USA, UK and China. Other governance-related activities obviously occur within the European Research Area, for example via the NEST FP6 programme (e.g. the TESSY "roadmap") and the European Academies Advisory Science Council report on synthetic biology (EASAC, 2010).

The influence of transnational research interactions is more than simple financial backing and resource exchange, but has also explicitly and implicitly changed the dynamics of global scientific governance. A more novel and probably more influential transnational endeavour has been the "international genetically engineered machines" (iGEM) competition. Section 6.4 gives a detailed discussion of the governance implications of iGEM. However, here, one small example may be helpful in elucidating the transnational nature of synthetic biology: on visiting an iGEM team in China in the summer of 2010, we learnt that communications among domestic teams are quite frequent. Not only were there formally organised national training camps and conferences, but students themselves also organised a nation-wide student-only workshop in Shanghai to informally test their ideas. We thus asked whether there had been any plans to set up a "national bank" hosting all past designs from iGEM teams around China to benefit future domestic teams. Both the tutor and fellow team members answered: "But why?

[2] See, for example, the conclusions of the BIONET project on ethical governance of research in the life sciences and biomedicine, led by LSE, and available at http://www.bionet-china.org/

There is no need. With BioBricks, we can get any parts we want quite easily. Plus, it directly connects us with all the data produced by iGEM teams around the world, let alone in China. A national bank would just be a more small-scale duplicate".

The point is not to say that the BioBricks Foundation's Registry is without problems. There are widely acknowledged difficulties with the quality of the parts in the Registry and concerns about its open source nature; and these are being addressed by the setting up of public and private "BioFabs", in the US and the UK, with parts produced and characterised by and for professional scientists as opposed to undergraduate students. The point is that such remarks are indicative of how grass-root scientists and a young generation of researchers perceive the 'national' and the 'international'. National research infrastructure (such as a national iGEM bank) is not considered a necessity and institutions with transnational stature (such as the MIT Registry) are considered a more efficient vehicle in facilitating research.

In summary, a fuller picture of the global development of synthetic biology, as with many other modern sciences, consists of both national particularities and increasingly entangled inter-national relations. These cross-border linkages do not represent a high proportion of the research activities and total research funding and it could be argued that most of the significant work is conducted in national settings, and that the USA dominates the field. We argue, however, that the influence of these entanglements on the global field is nevertheless significant and that their implications for governance are at least twofold.

Firstly, while national characteristics can still be traced, and the promotion of related research still relies on regional context and development paths, there is also a growing occurrence of governance propositions produced by multinational groups, cross-border financing strategies, and transnational administration of research infrastructure and data. In this sense, one could argue that as transnational communication becomes part of the social condition in scientific research, there is an emerging governmentalization (capacity to govern) of non-state actors.

Secondly, there seems to be an emerging shift in the way in which problems are perceived by different local, national and international authorities, and in the objectives they seek and the strategies and techniques that they choose to pursue. Globally speaking, the effective governance of synthetic biology requires not only that nation-states pass down their authority into a plurality of civil institutions and networks, but also requires nation-states to transform their authorities into other transnational agents (such as international conferences, iGEM and other cross-border research initiatives). This indicated need for a shift of governance ethos and practices will be further explained in Section 6 of this paper, in relation with the governance challenges examined below.

5. Key Governance Challenges

In the previous sections, we have identified and described two fundamental features of synthetic biology: scientific uncertainty (which goes beyond narrowly defined 'risk') and cross-borderness at multiple levels (not only disciplinary but also organisational, industrial and geopolitical). We now focus on explaining how these features present three key challenges for the governance of synthetic biology both at the national and international level:

a) the salience of both knowledge and non-knowing

b) the cultivation of external accountability

c) the fragmentation of authorities

There is no linear correlation between each of the two research features and these governance challenges. As shown in Figure 1 below, each element of synthetic biology is only one thread in a tangled and mutually constituent web of scientific practices. On the basis of an examination of these challenges and reviewing existing regulatory inefficiency, section 5.4 further analyses what these mean in relation to international governance initiatives.

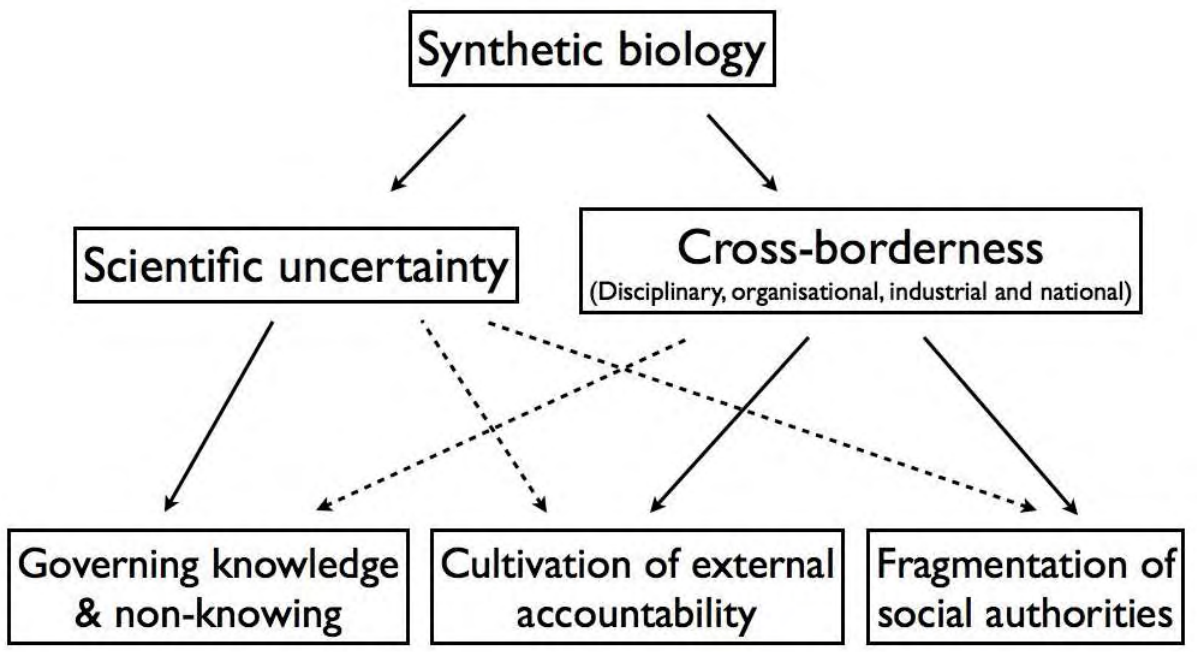


Figure 1: Features of synthetic biology research and subsequent governance challenges

5.1 The salience of both knowledge and non-knowing

The regulatory challenge of scientific uncertainty posed by synthetic biology has been recognised by many. Current responses to such challenges have mostly been broadening the policy consultation base and enhancing periodical scientific and ethical review. Some have also emphasised the importance of applying the precautionary principle (Parens et al., 2009). The meaning and implications of the precautionary principle for dealing with scientific uncertainty are extremely contested. Parens uses a particular definition which suggests that society should interfere with the development of an emerging technology when there is "good cause to suspect that it might cause serious physical harm" (Parens et al., 2009:26). In this particular interpretation of the precautionary principle, these interventions can be lifted only if and when further scientific findings prove no harm will result. This strategy and other proposed strategies for dealing with the scientific uncertainty embedded in synthetic biology vary in details but display a similar rationale: they assume that in order to produce better regulation, one needs to continuously fill in the knowledge gap with the latest scientific evidence. Whilst this non-ending pursuit of more knowledge for better regulation is important, reducing 'dealing with scientific uncertainty' to 'acquiring more knowledge' produces an unending quest for more and more knowledge, , because scientific uncertainties associated with modern science generally cannot be overcome by more knowledge but are rather the product of more knowledge.

The emphasis on evidence-based policy, also exhibited in other areas of the life sciences and nanotechnology, has constrained the way in which the possibilities for governance have been understood. Some believe that this limits the way in which governance problems are conceived to be merely an issue of securing public acceptance for technological developments; for example the pressure group GeneWatch UK argues that an over-reliance on scientific expertise creates a "political entrapment" (GeneWatch, 2009:2) that blinds policy-makers from comprehending new situations as anything other than "an obstacle that must be overcome, with more 'education' and policies which seek to make adoption of the relevant technologies inevitable" (Wallace, 2010a: 10). Moreover, contrary to clean-and-precise decision-making, a DEMOS report reminds regulators that "governance is a process of negotiating ambiguity, a messy business consisting of compromises, partial decisions and continuous renegotiation… Complexities are obscured by discussions of evidence and knowledge" (Stilgoe et al., 2006: 74). Whether or not 'evidence based policy' is ever anything other than a slogan or an aspiration, it must be recognised that in matters of science and technology, the vectors shaping policy making, and the time scale of policy formation and implementation, cannot be reduced to scientific evidence alone.

Given that scientific certainty can seldom be achieved, some have argued that in policy-making, "scientific authority is the problem rather than the cure" (Salter 2007: 287). To set policies and balance social needs on the basis of an all-around examination of scientific evidence is important, but it has limits. Over-reliance on a scientifically framed policy agenda has led to what Sheila Jasanoff termed "technologies of hubris", in which "the unknown, unspecified, and indeterminate aspects of scientific and technological development remain … treated as beyond reckoning, they escape the discipline of analysis" (Jasanoff, 2003: 239). In other words, an intrinsic limit in the current regulatory culture is that it automatically excludes the "unknown, unspecified and indeterminate" factors, which are an indivisible part of research reality. Debates and policy practice tend to "close down" these factors and reduce them to narrowly defined "risks" (Stirling, 2008 and 2010; Wynne, 1992).

We found evidence that "technologies of hubris" and the consequent narrowing of the agenda are currently at work in many discussions of synthetic biology. Questions about risks related to synthetic biology have been raised, but these have usually related to narrowly defined risk, and in most cases these have then been closed down by statements to the effect that at least in the foreseeable future, all applications of synthetic biology will be covered by existing regulations for genetically modified organisms (BBSRC, 2008a). While this is true in the strictest sense (genetically modified organisms produced by synthetic biologists will be covered by existing GM legislation), this reduces the issue to the kinds of narrow risks addressed initially by those regulations and the risk assessment procedures associated with them. Wider concerns about the kinds of social change embedded within the ways in which GM technologies are developed, commercialised and utilised are thus excluded. Such reassurance also fails to recognise that the risk assessment practices applied to GMOs have been

highly contested since they were introduced in the 1990s, in both the European Union and the USA; and how they have gradually had to adapt in response to public controversies to incorporate indirect, delayed, and cumulative long-term health and environmental effects, and effects on "agricultural habitats" as well as "natural habitats" (Levidow and Carr, 2005).

In summary, while governance based on knowledge is important, such a rationale alone is not enough to resolve the relevant uncertainties. We propose in Section 6 that it is equally important to complement current governance regimes with rationales that are oriented to the non-knowing aspects of synthetic biology: to upgrade governance capability, there is a need to 'open-up' uncertain aspects of science in order to enable them to have an explicit presence in governance.

5.2 The cultivation of external accountability

As synthetic biology relies on collaborative contributions from previously distant disciplines, it highlights the need for improving external accountability. That is, the "accountability to people outside the acting entity, whose lives are affected by it" (Keohane, 2003:141). This is opposed to the "internal accountability" which is based on ready-established chain-of command or pipelines of financial resources (Keohane, 2003:140). An example of internal accountability in synthetic biology would be that a principal investigator is held responsible to the commissioning institutions (such as the DOE in the US, the Research Councils in the UK and MOST in China) for the completion of a project and the authenticity of the research result. External accountability is to those, in the eyes of the practitioners, who are outside the practitioners' familiar field but who may influence or be affected by the practitioners' action. It is a social actor's (individuals, groups or organisations) acknowledgment of other's concerns regarding the actor's actions.

Because synthetic biology is multi-lateral interdisciplinary research, and involves crossing many kinds of borders, external accountability is required from a number of different kinds of 'others': scientists and engineers are 'others' to each other, as are for example: biologists and chemists, scientists and civil society groups, pharmaceutical and petroleum companies, etc. As has been pointed out earlier, currently most researchers still identify themselves with 'parent disciplines' and access to knowledge and support from other disciplines still need to be 'gained'. Synthetic biology practitioners have to work with others from distant disciplines and require financial/technical/political support from previous outsiders. Thus, while internal accountability is still of importance to synthetic biology, this paper highlights the need to promote external accountability.

This need is partially recognised in a worry summarised in a Woodrow Wilson Center report that "even well-motivated and competent scientists" may "fail to recognise risk factors outside of their area of expertise" and "overestimate the level of control they have" (Rodemeyer, 2009: 29). It is also stressed in the Report of the BBSRC/EPSRC Public Dialogue on Synthetic Biology, which states that "regarding regulations there was the need to open up control to the scrutiny of others" (Bhattachary, 2010: 13).

This is, of course, not to negate that good governance for synthetic biology requires establishing norms within a working group (such as research institutions) and enhancing accountability within an established profession. The point is that synthetic biology has highlighted enabling horizontal supervision and ensuring the external accountability of a certain working group to its interest-related neighbours (such as partner institutions, patient groups and private investors) are just as important. This is a point that has been touched upon through discussion on broadening policy debates and incorporating public engagement "upstream", but existing discussions focus almost exclusively on an ill-defined 'general public' as the key 'outsider' that needs to be 'engaged' with; and on a set of narrowly defined issues that those 'inside' synthetic biology can be ask to account for, namely biosafety, biosecurity and (ill-defined) 'social and ethical issues'.

It is important to note here that acknowledging the need to incorporate external opinions is different from an institutionalised means to establish external accountability. The reason is that the former approach emphasises feeding information into one acting entity (such as incorporating ethical, scientific and public opinion into 'the government'), with all initiatives in effect evolving around one

central actor. The latter is based on communicating information among two or more acting entities (such as constructing mutual trust between governments, scientific communities or civil society groups).

This point can be further demonstrated through a review of the three regulatory frameworks that have been discussed regarding synthetic biology (Kelle, 2007: 29):

a) government-led oversight and controls;

b) high reliance on bottom-up initiatives, such as self-governance; and

c) "a smart combination of self-regulation and government regulation" (de Vriend, 2006: 67).

While all these frameworks have their merits and strengths, we argue below that in their current forms they are inadequate for promoting and guiding external accountabilities of social actors.

a) Government-led oversight and controls

As mentioned at the beginning of this paper, despite a common emphasis that opinions from various civil groups should be recognised in the governance of synthetic biology, government is still seen by many as the leading actor in scientific regulations. For example, the UK is seen as relying on the Government to follow the Haldane Principle, in which rather than having the Government imposing scientific priorities, wide consultation and extended peer-review are incorporated into decision making. In practice, this operates as a process of decentralisation of power, where "the Government sets an over-arching strategy" at the top which is then followed by successive differentiations and divisions of regulatory authorities with "funding flows through the Research Councils" such as BBSRC, EPSRC and MRC. This forms an authority chain which radiates from one centre (the government) to different institutions and ultimately to "researchers themselves" (House of Commons, 2010: 8-10).

By consecutively incorporating other social sectors into the decision-making system at different levels, this government-led approach is able to institutionalise a growing number of social practices directly accountable to one authority, the Government. But such political rationale presupposes well-established institutional arrangements for assimilating collected opinions and translating them into political actions, which may not always be the case. More importantly, it may not be enough in answering the need for individual social groups to be accountable to and gain support from each other. In other words, it may not be enough to address questions such as the one quoted above from Drew Endy: how to gain access or transmit knowledge across (research) cultural divides? If "decentralising power" only means authority is diffused through a streamline from the centre rather than originating with support from fellow organisations, then established communities (such as biology, engineering or computing communities) may lack motivation in collaborating with each other. For example, even though UK Research Councils have promoted joint-funding initiatives across sectors traditionally governed by the separate (medical, biological, engineering, social, humanities) Research Councils, the Royal Academy of Engineering disapproves of funding schemes in "their present form" as merely "familiarising the awardees with the working culture of another discipline" and failing to facilitate individual researchers to develop more substantive roles across disciplinary borders (RAEng, 2009: 49).

This is not to say that "government-led oversight and controls" as a regulatory option cannot promote external accountability but to highlight that, at least in its current proposed form, external accountability among social institutions is still insufficiently attended to in proposals for government-led oversight. Simply incorporating external opinion and decentralising powers through branches which radiate from the government may not be enough to fully address the cross-borderness of synthetic biology.

b) Self-governance

As opposed to government-led regulatory options, there has also been the proposition of a bottom-up approach. Probably the most well-known example is the self-regulation initiative put forward at the SB2.0 conference, which modelled itself on an Asilomar mode of regulation. This proposal was eventually withdrawn due to the fierce criticisms from thirty-five civil society organisations (ETC, 2006). Yet it is important to note that what triggered the opposition was not self-governance per se. The "synthetic biohazard non-proliferation proposal" set by George Church (Church, 2004), the joint proposal for "options for governance" of synthetic genomes led by the Craig Venter Institute (Garfinkel et al., 2007) and the Industry Association of Synthetic Biology's workshop report on "Technical solutions for biosecurity in synthetic biology" (Bernauer et al., 2008) are also examples of self-governance initiatives, but none of these received the kind of opposition that the SB2.0 conference attracted.

NGO opposition to the SB2.0 initiative was not directed at scientists' ignorance of social implications since the background paper for self-governance focused on improving biosafety, biosecurity and promoting ethical obligations (Maurer et al., 2006). What was controversial was the declaration that "many options can be implemented through community self-governance without outside intervention" (Maurer et al., 2006: 2, emphasis added). But with a global increase of practitioners trained at different levels and conducting research with various implications, the global scientific community is no longer restricted to "the old boy's network" with straightforward agendas (Rabinow in Lentzos et al., 2009: 20). SB2.0's attempt to replicate a monopoly of internal administration as in the Asilomar experience does not "make much sense" (Rabinow in Lentzos et al., 2009: 20). It denies other social actors any role in auditing future scientific practices and was thus perceived as "anti-democratic" (ETC, 2006). Thus despite the initiative of incorporating broader concerns into internal codes of conduct, such self-governance schemes have failed to address the requirement of external accountability and this undoubtedly led to the subsequent antagonism from other social groups. In short, criticisms of the governance scheme proposed at the SB2.0 conference were not so much directed at self-regulation in general, but at its inattentiveness to sustained external accountabilities.

c) A combined approach: Professionalization

Researchers from the SYNBIOSAFE project point out that "contrary to our expectations, none of our respondents [scientists] opted for self-regulation by scientists as the most favourable solution; rather a large majority preferred a combined approach" (Ganguli-Mitra et al, 2009: 322; see also Kelle, 2007: 29). The reason, as indicated by another paper from the SYNBIOSAFE group, is that with the scientific uncertainty embedded in synthetic biology, to welcome "a combined approach" of governance is not so much about the surrender of scientific authority (in fact, scientists still play a dominant role in regulatory committees, review groups and policy consultation), but rather a (re)distribution of responsibilities among interest-related social groups (Schmidt et al., 2009: 6).

Collaborative research between Canadian and Australian social scientists has suggested professionalization as a governance strategy that "links the benefits of flexible self-governance to a public policy and legal framework" (Weir and Selgelid, 2009: 92). The 'profession organisations' in Weir and Selgelid's proposal do not include societies formed without authorisation of statutory laws. Rather, to act as a governing strategy, professionalization is based on "a legally mandated association granted a monopoly over specialized practices, a delimited authority delegated by sovereign states" (Weir and Selgelid, 2009: 92). The core rationale of this proposal is that by licensing practitioners on the basis of certain qualifications, professionalization can act not only as scientific oversight, but also as an enforcement mechanism in guarding public values. In other words, professional organisation, with its power to normalise behaviours within a profession and its legal accountability to the government, can act as a mediator for commuting moral obligations and negotiating social supports. Thus it "overcomes some of the polarities found in current debates about synthetic biology governance, in particular top down versus bottom up governance" (Weir and Selgelid, 2009: 96).

The downside of this specific proposal is that it sees political endorsement as the prerequisite to the emergence of a 'profession'. Yet at least in terms of science and innovation, the reverse situation is

more common: political developments tend to happen, not in advance, but in response to the development of a new practice (Guston, 2008). Furthermore, with the globalisation of research, in recent decades, national regulations often follow and adapt to international trends. Thus a heavy emphasis on national professionalization would be inadequate to address the dynamics of contemporary scientific practice.

More importantly, such arguments also neglect the fact that at least currently, synthetic biology is mostly done by scientific professionals who have received formal training and identify themselves with one of several parent disciplines. In other words, the problem is not so much an absence of professionalization or lack of statutorily authorised mediators to communicate social values and scientific pursuits, but the absence of efficient conversation channels among several professions with similar but separate cultures, codes of conducts and research priorities.

To summarise, this section analysed the three most frequently mentioned regulatory pathways (government-led, self-governance and a combined approach) in current synthetic biology debates. The aim of such analysis is by no means to suggest that these regulatory approaches are inherently wrong. But the point is to highlight why widening regulatory contributions and assimilating external opinions into decision-making processes alone are not adequate. Despite their merits, regulatory pathways such as decentralising power, exclusive self-rule and homogenising scientific practice all fail to tackle the cross-borderness of synthetic biology. Contrary to their emphasis on multi-participant governance, these regulatory initiatives are still, at least in their existing forms, in effect largely oriented to one-centre models of governance that fail to address the need to facilitate external accountability amongst social actors.

5.3 Fragmentation of social authorities

The third key challenge generated by scientific uncertainty and cross-borderness in synthetic biology is the fragmentation of social authorities. Contemporary science challenges and reconstructs the traditional relationship between regulator and those regulated; decision-maker and those affected by the decisions. This is even more so in the case of synthetic biology.

In a comprehensive review of the development of American administrative frameworks on biotechnology in the last three decades, Rodemeyer (2009: 45) concluded that the fundamental problems regarding synthetic biology are the constant inadequacy of information and the subsequent question of "whether agencies have sufficient resources, including scientific expertise, to carry out their regulatory responsibilities". In response to such a challenge, a number of specific suggestions have been made on what good governance of synthetic biology should incorporate, such as public engagement, especially upstream public engagement (Balmer and Martin, 2008; Pauwels and Ifrim, 2008; Parens et al., 2009), strategic funding for interdisciplinary network-building (RAEng, 2009; POST, 2008), maintaining open source repositories (NEST, 2005), facilitating standardization (EGE, 2009), establishing an international biosecurity clearing house (Maurer et al., 2006; Schmidt et al., 2009; EGE, 2009), segmenting research processes into different regulatory divisions (Kelle, 2007, 2009; Bedau et al., 2009) and licensing and registration procedures for DNA sequencing firms (Garfinkel, 2007). In addition, a roadmap has been envisaged towards a successful European synthetic biology (Gaisser et al., 2008). The situation, as not uncommon to cross-border governance initiatives, is that "what is absent, are not rules per se, but the consensus about which rules should be applied" (Hajer and Versteeg, 2005).

The dispute over whose rules to follow reflects a fragmentation of social authority. As science failed to provide certainty, the disappearance of the assumed single (scientific) authority within society has given way to the emergence of a number of competing authorities with different agendas. In the context of synthetic biology, some still emphasise that governance authorities have to comply with science. As the Royal Society of Chemistry's memorandum points out "unless good scientific and technical advice is taken into the policy making process, the process will yield policies that are not technically acceptable or, worse, not technically feasible" (RSC in House of Commons, 2010: Ev171). Others propose end-users should have a determinant voice in shaping research; for example one

European study on the science-industry-policy interface of synthetic biology concluded that regulatory criteria "cannot be invented by any (political) institutions or organisation in a top-down approach, but has to be developed by the users (academia and industry) themselves" (Gaisser and Reiss, 2009). Still others insist that synthetic biology is a "ramification" of human practices and should be operated within the conditions and constraints of the larger community (Rabinow and Bennett, 2009). Some NGOs argue that civil society should contribute at all levels "to evaluate and plan a coordinated response to the emergence of synthetic biology" (ETC, 2007: 50). The Report of the BBSRC/EPSRC Public Dialogue suggests that there "is a need to develop a different type of conversation [...] involving people (citizens, consumers, other users) not just at the end of the process but throughout" (Bhattachary, 2010: 12).

In each of these cases, different social actors are promoted as essential participants in the governance of synthetic biology; but each of these actors can only ever aspire to partial legitimacy: proximity to research experience, market, resources or political legitimacy does not guarantee entitlement to assume overall authority. It provides each social actor with leverage in exerting their influence, but at the same time such leverage remains partial and contested. Thus, the ability for any social institution to govern research practice remains partial and temporary and it is in this sense that authorities are fragmented.

5.4 Implications for international governance

It is useful to be reminded that the prime concern of this working paper is not to offer single-issue solutions (such as on risk assessment or IP protection), but to investigate possible routes to enable the governance of synthetic biology across different nations. Thus, it is beyond the ability and interest of this paper to provide detailed policy critiques on each individual concern synthetic biology touches on, for such topics benefit more from specialised discussions (such as Royal Society Science Policy Centre, 2009; IRGC, 2011). This report does not seek to identify common principles or conventions which should form the basis of synthetic biology regulations, for diverse social authorities would form their own value judgements according to specific contexts and traditions. In fact, many existing sociological inquiries have proposed combinations of general principles with slight variations. The latest and one of the most comprehensive sets are the five principles underlined by the US Presidential Commission for the Study of Bioethical Issues on regulating synthetic biology and other emerging technologies: a) Public beneficence; b) Responsible stewardship; c) Intellectual freedom and responsibility; d) Democratic deliberation and d) Justice and fairness (PCSBI, 2010).

As previously specified, this paper focuses on how international governance can be achieved and sustained, in order to steer the development of this emerging technology in the most effective manner. So far, this paper has specified the governance context for synthetic biology. This includes two key features (scientific uncertainty and cross-borderness) and three consequential challenges (knowledge vs non-knowledge; external accountability and fragmentation of authorities). As have been noted in previous sections, although many problems seem more acute and pressing due to synthetic biology's ubiquitous applications across industries, none of these challenges are unique to this field or particularly novel to transnational endeavours.

Here existing failures and successes of global management of nanotechnology and climate change may be of special relevance in conceptualising how these challenges can be better met. Because apart from scientific uncertainties and ongoing disputes over data interpretations, both of these cases, like synthetic biology, connect a large number of social sectors (health, energy, trade, agricultural, security, innovation etc.) and their potential impact cannot be contained by traditional institutions or national borders. More specifically, international efforts on nanotechnology and climate change have highlighted three general views on how actions of and interactions among global stakeholders may be better structured.

Firstly, the fundamental transformation required is, at least in the first instance, not organisational but institutional. This is to say, as suggested by long-term global environmental change studies, merely creating new international agencies, establishing special branches, or expanding existing programs is

of limited value. What is more important is appropriate institutionalisation of how clusters of rights, roles, interactions and decisions of stakeholders are identified, recognised and processed (Young, 2008). A Chatham House-commissioned study on nanotechnology also concluded that, new globally emergent innovation does not necessarily mean an immediate demand for new forms of international organization of governance (Breggin, et al, 2009; Falkner et al, 2009). In fact, for the time being, "political energies...would be better spent on strengthening existing forums for international coordination and adjusting domestic regulatory frameworks where needed" (Faulkner et al, 2009: 7). In short, in handling these transnational regulatory challenges, it is the governance ethos rather than organisational designs that are in more urgent need of change.

Secondly, cross-border governance requires certain collections of authorities as well as in-built social adaptiveness to contextual particularities. On this point, many lessons can be learnt from international environmental regulations. A key reason for the Montreal Protocol on Substances That Deplete the Ozone Layer turned out to be "the single most successful international agreement" was because of its style as a "portfolio of specific agreements" which, guided by the same mandate, attends to individual technologies or professions and "allows different agreements to be enforced in different ways" (Barrett 2010: 67, 70-71). In contrast, the failure of the Kyoto Protocol is often attributed to its attempts to solve the problem in one go: a wholesale of targets and timetables, with over-reliance on nation-states hierarchies (Barret, 2010: 67-70; Hulme, 2009: 290-3). Contemporary social studies of science have also repeatedly underlined the importance of adaptable regulatory system which can be responsive to technical uncertainties and evolving social needs. The Royal Commission on Environmental Pollution's report on nanotechnology has given special emphasis to the continual attentiveness to "social intelligence" which embodies the "deliberation among a wide range of different groups and members of the public" (RCEP, 2008: 73). In short, successful global governance requires directive but not definitive programs.

Thirdly, any sustainable global initiative should consider the reality of innovation and international trade. In responding to the US Presidential Commission' ethical stands on synthetic biology (PCSBI, 2010), 58 interests groups jointly criticise the Commission's replacing the precautionary principle with "prudent vigilance" and call for "a moratorium on the release and commercial use of synthetic organisms until a thorough study of all the environmental and socio-economic impacts of this emerging technology has taken place" (ETC, 2010). However, previous experience with nanotechnology has already suggested that "the solution...is not simply to impose a moratorium that stops development, but to be vigilant with regard to...how reversible is society's commitment to the technology and how difficult would it be to remediate if problems arose." (RCEP, 2008: 8). Similarly, the EU's environmental leadership cannot be perceived simply as a normative power primarily based on ideas and values, but is also still entangled with (and sometimes hampered by) various national economic interests (Falkner, 2007). In short, effective international initiatives need to be guided by acknowledging and mediating real world interests.

In summary, discussions on the salience of both knowledge and non-knowledge, the need to culture external accountability and the fragmentation of social authorities have suggested that traditional evidence-based policy has shown its limits, for the evidence required is not available at the times, places and in the forms necessary robustly to underpin governance rationales and strategies. Cross examinations with comparable global governance initiatives further indicates an adjustment in the governance ethos, which can steer the global agenda with directive but not definitive programs and also be attentive to reality on the ground. Thus we propose, as specified in the next section, that besides pursuing a scientifically informed bureaucracy, it may be time to bring back a sense of an art to governance. We argue that effective governance in the face of scientific uncertainty and cross-borderness is best framed, not as a rigid regulatory regime, but as a flexible and evolving 'art of governance'. Effective governance seeks to foster good science, not to hamper it, but recognises that good science goes hand in hand with open, clear, transparent regulation to ensure both trust and accountability.

6. The art of governance and governance as an art

It is perhaps necessary to clarify here the distinction between 'governance as a form of art' and 'art as an element of governance'. The latter can be generally seen as a contemporary art genre, in which artistic representations (e.g. paintings, sculptures, etc.) are used to reflect on life sciences. The former denotes a mode of activities which embodies some of the 'craftwork' ethos of artistic practice. It is this point that this paper focuses on. In fact, this emphasis on 'art' is entirely consistent with a long series of reflections on 'statecraft' which is usually defined as the 'art' of conducting the affairs of state, or the 'style of governing' with the aim to "regulate infrastructures... and to delegate powers" to relevant groups (Osborne, 1997: 175; 183). This paper further provides preliminary discussion on the basic tools that could support governance being practiced as an art.

Such an 'art of governance' seeks to facilitate effective interactions between the range of current and emerging social actors involved in or affected by scientific and technological developments, to ensure that all parties have the opportunity to express their perspectives and interests at all stages in the pathways of research and development, through transparent and democratic processes. The art of governance recognises that no decisions will suit all actors, but effective compromise depends on ensuring openness and transparency in the process by which decisions are reached, demonstrating genuine consideration of all perspectives.

On the basis of the previous analysis of the features of synthetic biology and the subsequent challenges they pose, this section examines four questions:

i) What is the subject of an 'artistic' (to paraphrase the familiar 'scientific') governance in the context of synthetic biology?

ii) What is the purpose of governance when performed as an art?

iii) What may be better presented?

iv) What should be left to the network actors to 'improvise'?

6.1 What is the subject of artistic governance?

Almost all existing policy reviews on synthetic biology open up their discussion with this question: what is the definition of synthetic biology. From the perspective of an evidence-based policy, this question is of great importance. The logic is that one could not regulate something without first stating exactly what 'the thing' is. For some, such as the European Group on Ethics in Science and New Technologies (EGE, 2009: 48, see also 36), "an internationally recognised definition of synthetic biology" is a prerequisite for sound regulation. However, in practice, this precondition of having a universally agreed definition may hamper rather than help the development of regulations. It has been highlighted that current regulations are "commonly assumed" as adequate "because it is not possible to define new fields neatly and draw boundaries around what is included or excluded" (OECD & the Royal Society, 2010: 12). Moreover, if we take the regulation of genetically modified organisms as an example, we can see that despite early efforts to define the GMO 'object', controversies over the boundaries of key regulatory categories such as GMO/non-GMO, contained use/deliberate release and experimental/commercial releases have plagued GM regulations, and these categories have had to evolve over time (often by becoming fuzzier rather than more sharply defined) to adapt the real-world practicalities (Bonneuil et al., 2008).

Instead of tying the development of governance to the requirement of a perfect definition, an alternative view (and one from the perspective of the arts of government) may be to see the subject of governance not as an 'object', but as 'interactions'. The same research practice may be recognised as "synthetic biology" by some and as "chemistry" or "genetic research" by others. Instead of getting electronic engineers and geneticists to all concur on the labelling of certain types of activity, a more effective governance approach may be to equip stakeholders with the techniques that will help enable effective coordination between those from very different and unfamiliar fields.

This may complement existing scientifically informed policies, or rather, stitch together regulatory patchworks currently dispersed among the various 'parent' fields for synthetic biology. For example, instead of instructing research practitioners by attempting to set out definitions for types of activity, and a formal 'code of conduct' or set of 'guidelines', it may be more fruitful to establish a set of 'guide questions' with the dual aim of helping to facilitate stakeholders' communication with others (what they should be aware of and entitled to know) and of clarifying stakeholders' accountabilities (under what condition their remit begins and ceases). This overlaps with the next point.

6.2 What is the purpose of governance when performed as a form of art?

Good governance is not just about encompassing reflexiveness in legislative documents, but also about continuously provoking reflexiveness among stakeholders. An analogy can be drawn from traditional artistic undertakings (such as cinema, novels, public exhibitions) that extend public discussion through exploring possible scenarios and in turn invite the audiences to reflect upon and construct real world alternatives (Chambers, 2005). The purpose of the 'art' of governance, then, is not to prescribe how things should be and to be restricted to certainty but to incorporate the scientific uncertainty and to elicit potential ways in which things could be.

Similar empirical initiatives specifically directed at science policy-making remain scarce. Some relevant examples can be found in a group of approaches that provide alternatives to traditional "technology assessment": "constructive technology assessment" (CTA) (Rip et al., 1995), "interactive technology assessment" (iTA) (Grin et al., 1997), and "real-time technology assessment" (RTTA) (Guston and Sarewitz, 2002). CTA, iTA and RTTA are broad approaches that usually require interactions between diverse groups of "enactors" involved in the development path of technologies (e.g. laboratory scientists, funders, regulators, end-users, affected groups). These approaches often incorporate scenarios building to encourage imaginative thinking about multiple possible futures. Such an approach, "does not so much set out to achieve a compromise between the interested parties" as to produce a "joint construction" of developmental plans (Grin et al., 1997: 82).

Another example of provocation of reflexiveness is a wide public consultation on synthetic biology organised by the BBSRC and EPSRC, which comprises stakeholder interviews and public workshops (Bhattachary et al, 2010). One of the main outcomes is the identification of "five central questions" which "should be incumbent on scientists to consider" (Bhattachary et al, 2010: 7, 12): "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?"; and "How do you know you are right?". A prime contribution of this interdisciplinary public dialogue is improving public understanding and the co-production of knowledge. Yet, what deserves equal attention is that, its final report highlights the importance of how such dialogical initiative "has begun to articulate some important questions of those developing the field" (Bhattachary et al, 2010: 89, emphasis added), which set the direction and accountability premises for regulatory undertakings.

The point here is to elucidate that when governance is performed as art, the aim may not always be to generate broadly based, scientifically framed and politically viable "orientational knowledge" (Kropp and Wagner, 2010: 824). It may also be equally important and constructive in seeking to identify 'orientational questions', which provide an alternative perspective in conceptualising and responding to science in-the-making.

Rather than trying to force the messiness of technical development into neat scientific definitions and pin down strategies for predicting the unpredictable, an 'artistic' governance approach enhances social resilience to scientific unpredictability. In the sense that governance is practiced as a way to entice social reflections on possible alternative scenarios, it matches Stirling's call to "open up" rather than "close down" the social appraisal of technology (Stirling, 2008). Through identifying key questions and pending scenarios, it encourages stakeholders to get prepared and to explore ways to handle impending situations. In this sense, governance is not merely an embodiment of reflexiveness, but the continuous provocation of reflexiveness among stakeholders. Effective global governance of synthetic biology may not rely so much on a chain-of-command or treaty-based establishment, but may be promoted through a transnational joint production of 'orientational questions'. When complemented

with an artistic approach, governance ceases to be an endless chase of scientific evidence in the hope of temporarily negating non-knowing. It becomes a direct political engagement with non-knowing.

6.3 What may be better presented?

As many have argued, governance refers to the interactive relationship between and within power-structures (government) and civil society (non-governmental forces) in a civil public realm to make decisions (Stoker, 1998:38-40; Abdellatif, 2003: 2-4; Hyden et al., 2004:16-17). As with the experience of GMOs, stem cell research, and nanotechnology, the most prominent inter-relations within the synthetic biology context is encapsulated by public engagement initiatives. "Upstream engagement" argues a Woodrow Wilson Center study, "could influence research priorities, provide critical feedback on hypothetical future applications and, perhaps most importantly, be used to establish and test processes and mechanisms that will respond to or deal with issues as they arise. On this understanding, public engagement becomes a kind of governance" (Parens et al., 2009:22).

There are frequent calls (especially in the UK and Europe, less so in the USA or China) for more and better public engagement (RAEng, 2009; EGE, 2009; House of Commons, 2010) to "enable the voice of different sectors of society, typically non-specialists…to inform and influence the development" (RAEng, 2009: 47). But, one study has highlighted the fact that the influence existing forms of committee reports and civil group recommendations have on European synthetic biology community is far from satisfactory (Kelle, 2007), and the recent BBSRC/EPSRC Public Dialogue has been criticised by some on similar grounds (Wakeford and Haq, 2010). Recent European regulatory culture has been criticised by Torgersen (2009: 12, 15) as "incorporating stakeholders" in "talking over governance", rather than having public opinions "embedded" in the governance of research development. In short, despite the growing attentiveness to public engagement, practice seems to resemble mostly a variation of broad-base conversation, or worse, public education (Wallace, 2010b) or public attitude research. There seems to be little that these endeavours, as currently formulated, can contribute to the governance of research practice.

This gap between scientifically implemented communications and deliberative output may again be better supplemented by an 'artistic' approach. One of the reasons for "a sustained campaign of public relations" (Royal Society of Edinburgh in House of Commons, 2010: Ev129), as has been demonstrated in this paper, is that in the absence of scientific certainty and presence of cross-borderness, social authorities are fragmented. This requires social groups to be accountable to and gain support from each other. Current policies may well have incorporated a variety of public input. Yet if regulation merely transforms diverse opinions into a uniform voice, it removes the linkage and interconnections between social actors. Thus conventional evidence-collection on 'who said what' needs to be extended to relation-tracing on 'who did what to whom'.

To put it in another way, for any forum in which individual social actors enjoy a genuine opportunity to influence other social actors' behaviour, having power-leverage is a necessity. But visualising power-leverage is just as important. This is to say, making visible the ways in which public opinion is incorporated into governing strategies, the where and the how of such incorporation, the ways in which effects over time can be made evident, and practice and mechanisms modulated in the light of experience.

6.4 What should be left to network actors to 'improvise'?

So far, this section has demonstrated that the 'art of governance' proposes a complementary focus on interactions as well as on actions. It also proposes bringing back scientific uncertainty and visualising interconnectedness in the development of regulatory strategies. What it does not propose to do, however, is to (pre)determine which social institution(s) should be entitled to and entrusted with the task of governing scientific practice. Indeed as the development of synthetic biology relies on continuous input from an expanding range of social actors, its governance reality resembles less of a

traditional 'technocratic decision model' and more of a 'palaver model', in which it is "unclear who may not contribute to the discussion" (Beck, 2007[2009]:125; emphasis added).

The question of who to include (and consequently exclude) in the governance of science, technology and risk is one that many existing regulatory initiatives have attempted to resolve – for instance what role should pressure groups, activists, religious minorities and so forth be assigned to in these processes? But as demonstrated in Section 5.3, traditional chain-of-command rationales, or a simple centre-periphery 'order' around leading institutions (government, scientific community or professional agencies), each of which establish and presume a fixed hierarchy of rights and credibilities seem to be insufficient. For in the case of new technologies, social authority is dispersed among diverse, and sometimes incomparable, social sectors, whose influence over other actors remains partial, contested and often inconsistent. It has long been acknowledged that a governance framework may be better constructed on a 'power with' rather than 'power over' model (Guinier 2002 in Slaughter 2004: 207). The UK's effective governance on stem cell research has confirmed the benefits of 'powering with' key institutions. For example, the UK's Human Tissue Authority has not been the host, but a participant within a number of networks that span across scientific, ethical, regulatory and industrial communities (HTA in House of Commons, 2010: Ev125).

Apart from strengthening governance capacity by broadening regulatory networks, the cross-borderness and novelty of synthetic biology may further add a 'temporal' dimension to the idea of 'power with'. This is to say, it may require a governance ethos that is not limited to embracing established groups across professional spectrums, but as is also ready to acknowledge, incorporate and exploit "new, unforeseeable" governance bodies in-the-making (Callon et al, 2001[2009]: 242). That is to say, it is not possible to anticipate who, or what, may become interested parties in debates around the governance of emerging technologies, and no-one should be excluded in advance.

One existing example that signals a need for such transition is the iGEM competition. The first iGEM competition occurred in the same year (2004) as the first international scientific conference on synthetic biology (SB1.0) and has since then been attentive in placing this novel research within its current and future social context. As iGEM functions as a global hub for young scientists to meet and compete, many nations, including China and the UK, have seen taking part in iGEM as a strategic move to promote domestic progress in the life sciences (POST, 2008; Zhang, 2008). Undergraduates' annual performances at iGEM contests have been treated as important indicators to assess, reflect on, and criticise national policy making. Meanwhile, it generates debates about what can/should count as good "human practices" and also facilitates global exchange and dissemination of concerns over biosafety, biosecurity, IP regimes, ethics and public engagement in the field of synthetic biology. Through participating iGEM competitions, countries like China and Japan, who have not traditionally attended to such issues so early on in the development of scientific fields, appear to be doing so for synthetic biology.

The increasing influence iGEM has over global development of synthetic biology relied on at least three points that may appear to be "counter-intuitive" to conventional governance approaches. Firstly, iGEM serves as a "scientific building block" (Falkner et al, 2009) that largely depends on unsystematic contributions from "beginners" (students and many of their tutors) rather than institutionalised experts. The concept of a "scientific building block" was highlighted in both the studies of nanotechnology and climate change. It refers to a transnational body that defines and characterises new materials, metrology and testing methods, and provides ground for internationally standardisation and regulatory convergence (Breggin et al, 2009: 85-87; Falkner et al, 2011). Regulators and experts are conventionally conceptualised as the primary members of such building block. However, in the case of synthetic biology, evolving standards, codes of conducts, collections and categorisations of BioBricks are at least as much influenced by the iGEM competition as by conventional scientific institutions. During the SB4.0 conference, Ron Weiss expressed the view that it is not yet clear "what synthetic biology is, but the process of educating new members of the community through iGEM was a process of learning about synthetic biology" and "the way of moving synthetic biology forward was to move iGEM forward" (Calvert, 2008). In short, the first counter-intuitive situation is that international normalisation of synthetic biology is not so much substantiated by established senior scientists but by "beginners".

Secondly, despite being essentially a 'scientific' competition, iGEM plays a crucial role in the 'social' engineering of the upcoming generation of young scientists. As pointed out in previous sections, iGEM actively promotes 'open source' through its link with the Registry of Standard Biological Parts. It is seen as a potential force in transforming global open access culture (OECD and the Royal Society, 2010: 25). Furthermore, iGEM is seen as positively "increas[ing] the exposure of synthetic biology to the public" (RAEng, 2009: 52) by incorporating a requirement and a special prize for "Human Practices" alongside scientific excellence. Not only are students encouraged to reflect on their research's social implications, but social scientists working in the field of synthetic biology also participate in the iGEM competition as team participants, team advisors, observers and judges for the Human Practices prize. The point here is not to assess iGEM's social contribution per se. Rather it is interesting to juxtapose what has been improvised by iGEM with the common 'filling the prescription' approach (see in Section 2.2), in which scientific and ethical/social governance are compartmentalised separately in designing bureaucracies for regulating technology.

Thirdly and most importantly, the influence iGEM exerts is not a political endowment by any nation-state or professional community, but has arisen processually, through the external accountability iGEM has developed with various stakeholders around the globe. In fact, when envisaging a governance structure for synthetic biology, few would initially have thought that an undergraduate competition would, or should, play a role. However, currently few policy analyses nowadays would ignore the central role iGEM has over the formation of international research culture in this emerging area (House of Commons, 2010; OECD and the Royal Society, 2010; RAEng, 2009).

The case of iGEM is only an example of how the reality of synthetic biology is urging us towards a transformation in conventional governance ethos. It is too premature to conclude what enduring influence iGEM will exert in the global governance of synthetic biology. Yet the growing attention iGEM has attracted internationally clearly indicated the possibility and practicality of a non-expert-led, non-previously-conceived (or even imagined), self-evolving associations in shaping the global governance of science. Rather than institutionally designing a calculated regulatory efficiency, it may be better to leave the regulatory structure open-ended and see what network interactions would 'improvise'.

Thus, for the governance of synthetic biology, instead of establishing a (or a set of) pre-configured international governance institution(s), efforts may be better spent in close monitoring of and responding to the evolving regulatory roles of various interests-related bodies. National institutions and certain transnational organizations may have an advantage in conducting large-scale long-term monitoring. Instead of disputing what should be the leading institution or who should be given more regulatory credits, the reality of synthetic biology may benefit more from more or less continuous tracking and periodically reviewing, adjusting and publicising the evolving collection of regulatory bodies at work. This may provide better stewardship for small domestic stakeholders to comprehend the global map of emerging science and clearer guidance in transnational coordination.

7. Concluding words

Every new technology opens up new situations. Yet this 'newness' is seldom completely novel or distinct. Modern technologies share many core characteristics and subsequently lead to many similar governance challenges. As has been noted by many social scientists and policy makers, it may be more beneficial to align seemingly separate social discussions to develop a more general approach addressing common themes.

The governance of synthetic biology provides a good opportunity to develop such a general approach. As an emergent technology, synthetic biology presents a developing field in which new governance strategies can be explored and a comprehensive regulatory apparatus is yet to be established. As synthetic biology seeks to position itself at the convergence of multiple research disciplines, unsettled governance problems from contributing disciplines may become more acute while previously settled issues may need to be reinvestigated. Rather than chasing dozens of loose-ends from the onset, there is an essential need to reflect on the common themes of these dilemmas. In addition, the prevalence of conflicting, even contradictory, narratives for synthetic biology suggests that current evidence-based nation-state governmentality alone will not be sufficient to comprehend or address the reality of these developments. There is a need to adjust regulatory outlooks and seek complementary governance approaches.

Consequently the main aim of this paper has not been to compile a list of specific issues and speculate on how they should be handled individually. It has been to investigate the root of these issues, identify core challenges and to provide preliminary discussion on how these challenges can be addressed at a general level. In the process, this paper has, in effect, covered most of the concerns under discussion and reviewed most of the published regulatory initiatives. In this way, it lays the groundwork for future investigations and outlines basic guidance for regulations in more specific contexts.

The main challenges to global governance of synthetic biology found by this paper are a) the governance of non-knowing; b) the cultivation of external accountability and c) the fragmentation of social authority. This paper argues that in addition to the pursuit of a scientifically informed bureaucracy, it may be time to bring back a sense of art to governance, which provides orientation while as the same time invites exploration. More specifically, the findings can be summarised as follows:

1. Taking into account non-knowing has become as vital as utilising the best available scientific knowledge. Filling knowledge gaps or fixing knowledge inadequacy remain important. But this only indirectly addresses the problem of non-knowing. To directly incorporate non-knowing into governance, an additional dimension should be added in which regulatory practices do not rely on scientific knowledge but build social resilience to non-knowing through continuous provocation of reflexiveness among all stakeholders. Effective global governance of synthetic biology may be promoted through transnational joint production of 'orientational questions'.

2. The field of synthetic biology, with its cross-borderness and scientific uncertainty, constitutes a loosely connected network of actors, each of whose authority is only partial and temporal. This fragmentation of social authority not only transcends national borders, but also transcends simple top-down or central-peripheral orders. Interest-related parties, including national sovereignty, are only one set of the authorities in the entangled web of global stakeholders. Thus in any forum in which individual social actors enjoy a genuine opportunity to influence other social actors' behaviour, having power-leverage is a necessity; but visualising power leverage, especially making visible the ways in which public opinion is incorporated into governing strategies, is just as important.

3. As the international arena of synthetic biology constitutes previously distant disciplines and socially detached sectors, the legitimacy and political influence of any given actor in governing synthetic biology can no longer be pre-determined or calculated in advance according to some fixed scale. Rather it requires to be gained in situ through successions of cross-border communications and undertakings. Instead of establishing a (or a set of) pre-configured international governance institution(s), efforts may be better spent in close monitoring of and responding to the evolving regulatory roles of various interests-related bodies. The reality of synthetic biology may benefit more from tracking and periodically reviewing, adjusting and publicising the evolving collection of regulatory bodies at work.

In short, effective governance concerning synthetic biology may only be attained when regulators attend to these more fundamental questions. The findings of this paper indicate that scientific uncertainty and cross-borderness can be better attended to when current scientific bureaucracy is supplemented by an 'artistic' form of governance.

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Annex I: Reports related to the governance of synthetic biology

Date	Region	Organizations	Title
2004 Jun	USA	George Church, Harvard Medical School	A Synthetic Biohazard Non-proliferation Proposal (18Jun 2004; updated 21May 2005)
2005	Europe	NEST (New and Emerging Science and Technology)	Synthetic biology: Applying engineering to biology, Report of a NEST High-Level Expert Group
2006 Sept	Europe	SYNBIOLOGY	An Analysis of Synthetic Biology Research in Europe and North America: Final Report on Analysis of Synthetic Biology Sector
2006 Dec	USA	NSABB (National Science Advisory Board for Biosecurity)	Addressing biosecurity concerns related to the synthesis of select agents
2006 Dec	Europe	Rathenau Institute	Constructing life: Early social reflections on the emerging field of synthetic biology
2007 Jan	Canada	ETC Group	Extreme genetic engineering: An introduction to synthetic biology
2007	Europe	NEST	Synthetic biology: A NEST pathfinder initiative
2007 Oct	US	J. Craig Venter Institute, Massachusetts Institute of Technology, and Centre for Strategic and International Studies	Synthetic genomics: Options for governance
2007 Nov	UK	Royal Society	Synthetic biology call for views - submissions
2007 Nov	Europe	IDC (Organization for International Dialogue and Conflict Management)	Synthetic biology & biosecurity: Awareness in Europe
2007 Nov	Europe	Rathenau Institute	Constructing life: The world of synthetic biology
2008 Jan	UK	POST (UK Parliamentary Office of Science and Technology)	POSTNOTE: Synthetic biology
2008 Apr	Europe	IASB (Industrial Association Synthetic Biology)	Technical solutions for biosecurity in synthetic biology
2008 May	Europe	SYNBIOSAFE	Background document for the SYNBIOSAFE e-conference
2008 Jun	UK	Royal Society	Synthetic biology: Scientific discussion meeting summary
2008 Jun	UK	BBSRC	Synthetic biology: Social and ethical challenges
2008 Oct	UK	BBSRC	Synthetic Biology Regulators' Meeting: Public statement
2008 Oct	Canada	ETC Group	Commodifying Nature's Last Straw? Extreme Genetic Engineering and the Post-Petroleum Sugar Economy,
2008 Sept	USA	Woodrow Wilson Centre	Awareness of and attitudes towards nanotechnology and synthetic biology: a report of findings
2008 Dec	USA	Woodrow Wilson Centre	Trends in American and European press coverage of synthetic biology: Tracking the last five years of coverage
2008 Dec	Europe	TESSY (Towards a European Strategy for Synthetic Biology)	TESSY Achievements and Future Perspectives in Synthetic Biology
2009 Mar	USA	Woodrow Wilson Centre	New life, old bottles: regulating first-generation products of synthetic biology
2009 Jun	UK	Royal Academy of Engineering	Synthetic biology: Public dialogue on synthetic biology
2009 Jun	USA	Woodrow Wilson Centre	Ethical issues in synthetic biology: An overview of the debates

Date	Region	Organizations	Title
2009 Jul	UK	Lloyd's Emerging Risks Team	Synthetic biology: Influencing development,
2009 Oct	Europe	IRGC (International Risk Governance Council)	Emerging risks: Sources. Drivers and governance issues
2009 Nov	Europe	EGE (The European Group on Ethics in Science and New Technologies to the European Commission)	Ethics of synthetic biology
2010 Mar	Europe	IRGC	Risk Governance of Synthetic Biology
2010 Mar	UK	House of Commons	Bioengineering seventh report of session 2009-10: Report, together with formal minutes, oral and written evidence
2010 Mar	UK	GeneWatch	Bioscience for Life? Who decides what research is done in health and agriculture?
2010	UK& OECD	OECD& Royal Society	Symposium on opportunities and challenges in the emerging field of synthetic biology: Synthesis report
2010 Apr	USA	NSABB	Addressing biosecurity concerns related to synthetic biology
2010 Jun	USA	Woodrow Wilson Centre	Trends in synthetic biology research funding in the United States and Europe
2010 Jun	UK	BBSRC, EPSRC, ScienceWise and TNO-BMRB	Synthetic Biology Dialogue
2010 Dec	US	PCSBI (Presidential Commission for the Study of Bioethical Issues)	New Directions: The Ethics of Synthetic Biology and Emerging Technologies
2010	Europe	EASAC (European Academies Science Advisory Council)	Realising European potential in synthetic biology: scientific opportunities and good governance
2011 Jan	Europe	IRGC	Guidelines for the Appropriate Risk Governance of Synthetic Biology
2011 March	USA	Executive Departments and Agencies (Office of Science and Technology Policy, US Trade Representative, Administrator Office of Information and Regulatory Affairs)	Principles for Regulation and Oversight of Emerging Technologies