1. Introduction

1.1 INTRODUCTION

On 20 May 2010, scientists in the United States announced that they had made the world’s ‘first self-replicating synthetic bacterial cell’.\(^1\) This achievement is the most famous outcome of the emerging field of synthetic biology.

Synthetic biology is a burgeoning field which draws on molecular biotechnology, biochemical engineering, genomics and information technology to create new tools and techniques. It offers to transform how we tackle our most difficult global problems, through applications such as greener energy and synthetic vaccines. However, it also poses risks such as damage to the environment, bioterrorism, and harm arising from ‘do-it-yourself biology’. As leading biologist George Church has pointed out, ‘For all the benefits it promises, synthetic biology is potentially more dangerous than chemical or nuclear weaponry, since the organisms can self-replicate, spread rapidly throughout the world, and mutate or evolve on their own.’\(^2\) Vast amounts of public and private funding are being invested in synthetic biology research, with this field being identified by *Technology Review* as one of the top ten breakthrough technologies most likely to change the world.\(^3\)

The accelerating pace of scientific research and uncertainties about the risks and benefits create complex challenges for regulation. What should the law try to achieve when new technologies emerge? Does a new technology require a new regulatory approach? How can the law possibly keep up with the science? How should scientists be involved in developing regulation and policy? Who should be able to access the technology?


\(^3\) Katherine Bourzac, ‘Synthetic Cells’ (2011) 114(3) *Technology Review*, 56.
How can regulation be used to promote innovation that benefits us all, while protecting us from harm?

This book explores the interplay between law and emerging technologies by analysing these questions in the synthetic biology context. As synthetic biology promises transformative benefits, but also poses risks of harm, these are critical issues to address. They are questions that matter not only to scientists and lawyers. They are also being grappled with by governments around the world, the biotechnology industry, environmentalists, bioethicists, philosophers, sociologists, and the public as end-users such as patients.

Synthetic biology aims to create novel organisms and biological systems which do not exist in nature, and to redesign natural organisms in substantial ways. This field is revolutionary in the new tools and techniques it offers and in the scale at which it allows us to experiment with biology. We are now able to modify organisms to a much greater extent than was possible with traditional genetic engineering. Scientists have moved from modifying one or several genes to being able to make large-scale changes to genomes, or even design and build completely new synthetic genomes. Synthetic biology is part of a new industrial revolution, ‘the information-genomics revolution’.

Synthetic biologists aim to make biology ‘easy to engineer’, to make organisms more like machines. ‘Synthetic biology’ is really a collection of approaches to this goal: building biological machines from bricks of deoxyribonucleic acid (DNA), building human-made genomes and cells from scratch, and using large-scale genetic engineering to make new products. These approaches are supported by the emergence of technologies that allow us to write and build DNA to our own designs.

During the short history of synthetic biology, there have been two moral panics arising from new developments in the field. Both developments related to research of the J Craig Venter Institute (Venter Institute). In 2006, the Venter Institute identified the smallest, most streamlined set of genes required for a particular bacterium to survive in a laboratory:

---


5 Church and Regis (n 2) 152, 210.

Introduction

‘the minimal bacterial genome’. This was followed by a patent application, and a related application for ‘synthetic genomes’. A panic ensued regarding whether such things could rightly be owned, and whether these patents might hinder scientific research.

The second panic occurred following the 2010 announcement that a ‘self-replicating synthetic bacterial cell’ had been created at the Venter Institute. This was publicised prominently and followed by explosive media coverage that triggered a wave of policy discussion in the US and around the world. The announcement alerted people to what could become possible with synthetic biology. Many would not have heard of synthetic biology prior to 2010, but the synthetic cell announcement brought the field and its implications sharply into focus.

This announcement was game-changing for debates not only about synthetic biology, but also about regulation of the biological sciences generally. In the United States, President Barack Obama joined the ensuing debate. His Presidential Commission for the Study of Bioethical Issues (the Commission) was tasked with investigating ‘the implications of this scientific milestone, as well as other advances that may lie ahead in this field of research’. It was directed to consider ‘the potential medical, environmental, security, and other benefits of this field of research’, in addition to considering its risks. As Obama stated, ‘it is

---

11 Ibid.
vital that we as a society consider, in a thoughtful manner, the significance of this kind of scientific development’.12

These two episodes have highlighted the issues to be explored in this book: the controversy over the risks and benefits of synthetic biology and the regulatory challenges created by this technology as it emerges. By understanding these challenges, we can move towards developing law that protects us from synthetic biology’s risks, while capturing its potential to improve our world.

1.2 THIS BOOK’S PROJECT

This book lays the groundwork for bespoke regulation of synthetic biology. It considers to what extent the technology and its social context are distinctive from those of earlier technologies. It examines the regulatory issues that arise from the emergence of this new field, with a view to identifying the key regulatory challenges and exploring the extent to which these are distinctive. It analyses whether synthetic biology can be regulated within existing regulatory structures or whether new mechanisms are needed.

While new technologies emerge into an environment where there are existing regimes developed to regulate earlier technologies, these regimes should not merely be ‘mechanically transplanted’ to apply to a new technology.13 In synthetic biology’s case, the existing regimes address genetic engineering and other previous biotechnologies. Of course, we should recognise ‘common regulatory challenges’, which arise for emerging technologies generally.14 Nonetheless, when a new technology like synthetic biology emerges, it will be necessary to consider the application of existing regulation and whether this is sufficient to address the new technology, including its impact on health, safety and the environment.15

While not wishing to ‘reinvent the regulatory wheel’, it is important to

12 Ibid.
14 Ibid., 30–32.
understand whether particular technologies present their own distinctive problems’. This involves asking whether new or specific regulation is required.

The main criteria to consider are legitimacy of the regulatory regime, its effectiveness, its ‘prudence’ or response to risk, its ‘connection’ or ability to keep up with the science, and its ‘cosmopolitanism’ or ability to deal with differing values and approaches internationally. These criteria can be used to identify the regulatory ‘hot spots’ or ‘pressure points on regulators’. I will draw on them to assess the regulatory challenges posed by synthetic biology, the adequacy of existing regulatory regimes, and potential solutions to the challenges. This discussion will focus significantly on regulatory effectiveness and connection. These are the main areas of regulatory challenge for synthetic biology at this stage in its development. The pursuit of procedural legitimacy through public consultation and discussion is also a key consideration in this work.

This discussion will draw primarily on legal analysis, but also on science policy, sociology of science, and the science itself. Considering the regulatory challenges posed by a technology also requires considering whether the technology itself is distinctive in some way. Accordingly, this book critically examines the complex and shifting science of synthetic biology, the emergence of the field, its key drivers and its potential impacts. An understanding of how synthetic biology departs from other scientific fields will contribute to developing a picture of the regulatory challenges it poses.

The US has been a focal point of both scientific research efforts and policy discussions and is the focus of much of the discussion in this book. A number of large reports into synthetic biology have been released in various jurisdictions including the US, the UK and the EU.

16 Roger Brownsword, Rights, Regulation and the Technological Revolution (Oxford University Press, 2008), 27; Brownsword (n 13) 30–32.
17 Brownsword (n 13) 31.
18 Ibid., 31–2.
20 Brownsword (n 13) 31–2.
The Presidential Commission’s report is the most thorough and detailed of these considerations and I will analyse and critique its recommendations in depth.

Two key scientific figures appear repeatedly throughout the story of synthetic biology told in this book; those of J Craig Venter and Drew Endy. They are both leading scientists in the field of synthetic biology. Venter has been a visionary and divisive figure in biotechnology for several decades. He is in favour of the aggressive use of the patent system and light-handed governmental intervention in synthetic biology. Drew Endy has been at the helm of the engineering approach to biology since the early 2000s and has founded key synthetic biology institutions to be discussed in this book. Endy has taken a leading role in community development and engagement with the legal and ethical issues raised by synthetic biology. He is a critic of intellectual property and has strived to introduce arrangements for sharing in synthetic biology. These two figures are important in the story of synthetic biology because of the differing approaches to regulation and intellectual property they represent, and their key role in shaping not only the science of synthetic biology but also the regulatory debate surrounding it.

This book forms part of a wider effort to investigate, understand and respond to the issues raised by emerging technologies. In addition to legal issues, there are also issues of politics, justice and public consultation. There are issues regarding promotion of innovation and technology transfer. There are also ethical issues in relation to manipulating and patenting living things, and philosophical issues regarding whether synthetic, human-made organisms are actually ‘life’, and how they will impact upon our understanding of ourselves. There are issues regarding the impact of synthetic biology-based industry on traditional methods of production, and impact on land use and livelihoods in the developing world.\(^{22}\)

---


Some existing scholarship in relation to synthetic biology has focused on these ethical, sociological and political perspectives, with less discussion of legal issues. Legal discussion has tended to consider the individual regulatory issues in isolation. This book extends the boundaries of discussion of synthetic biology to include greater consideration of regulatory issues and explore the extent to which the regulatory challenges posed by synthetic biology are distinctive.

1.3 STARTING POINTS – THE ROLE OF REGULATION OF EMERGING TECHNOLOGIES

Answering the questions posed in this book requires, as a starting point, considering what the role of regulation should be in relation to emerging technologies. I have begun from the position that regulators and regulation properly have a dual role: both in maximising the benefit to the public from emerging technology and minimising its potential harms.\(^{23}\) That is, the role of regulation encompasses managing of issues of risk associated with a new technology, but also facilitating societally beneficial innovation.\(^{24}\) This means that ‘It falls to politicians and regulators, and ultimately to the law, to set the limits of technological innovation, to co-ordinate the assessment and management of risk, to design procedures for public participation, and to set the terms of compensatory responsibility.’\(^{25}\)

Regulation thus has a role in both constraining and enabling the development and use of the technology. In relation to regulation’s facilitative role, it ‘falls to regulators and the law to establish a governance environment that is supportive of desirable technological innovation and that ensures the benefits are fairly shared’.\(^{26}\) The goal is for ‘law and technology … to work together to improve the basic conditions of human social existence’.\(^{27}\) To do this, we need a regulatory environment that

---

\(^{23}\) Following Brownsword and Somsen (n 19), 2–3.

\(^{24}\) Ibid.

\(^{25}\) Ibid., 2.

\(^{26}\) Ibid.

\(^{27}\) Ibid., 3.
promotes beneficial innovation, the deployment of such technologies and benefit-sharing, while also allowing us to manage risks.\textsuperscript{28}

This conception of the role of regulation in relation to emerging technologies is drawn from the work of regulatory scholars Roger Brownsword, Han Somsen and Morag Goodwin. It is based upon the idea that, in democracies, the development of science and technology occurs with a social licence – a sort of permission from society – which is subject to constraints imposed by protection of human rights and human dignity.\textsuperscript{29} The Commission also pointed out the responsibility of scientists to society:

Society as a whole has a stake in what scientists and engineers do. In turn, scientists and engineers should recognize the potential impact of their research on those who will experience both its benefits and burdens and their responsibility to those who provide the means, directly or indirectly, for their research.\textsuperscript{30}

In considering regulating for societal benefit through technological innovation, I have also taken inspiration from the work of regulatory scholar Hailemichael Demissie. Demissie has proposed that for nanotechnology regulation, the focus on risk management needs to be supplemented with a distinct discourse and regulatory jurisdiction for benefit management.\textsuperscript{31} Discussion of emerging technologies can tend to focus on risk, to the detriment of consideration of benefit issues.\textsuperscript{32} Taking ‘regulating for the positives’\textsuperscript{33} as part of the role of regulation in relation to emerging science is preferable because it acknowledges that emerging technologies present potentially transformative benefits as well as risks.

For these reasons, the role of regulation of synthetic biology should be considered more broadly than as management of risk and setting of limits on scientific development. The discussion in this book is aimed at promoting the beneficial development of the synthetic biology at the

\textsuperscript{28} Ibid.; see also Brownsword and Goodwin (n 15) 46.
\textsuperscript{29} Brownsword and Somsen (n 19) 2.
\textsuperscript{30} The Presidential Commission for the Study of Bioethical Issues (n 10) 141.
\textsuperscript{32} See, e.g., ibid., 137–41.
\textsuperscript{33} Brownsword and Somsen (n 19) 49.
research stage, by looking into the issues of intellectual property, ownership, and sharing of information.

Reflecting the dual goals of regulation, I will divide the discussion of particular regulatory challenges posed by synthetic biology into regulation for the risks (Part II) and regulation for the benefits (Part III).34

As a further starting point, it is necessary to consider the role and aims of science in a liberal democratic society. That is, why do we ‘do’ science? A key role of science is to improve the public’s well-being and happiness35 through the pursuit and generation of knowledge of our natural world, development of beneficial technologies, and economic stimulation. While recognising that not all scientific developments turn out to have publicly beneficial uses, and that some can be put to dangerous use or misused in potentially dangerous ways, my starting point is that the overarching role and objective of science in a democracy is the improvement of collective well-being and happiness. This is a societal view of the benefit to be obtained from scientific innovation. Indeed, ‘the regulation of biotechnology should be guided by a concern for the common good’.36

In the specific case of synthetic biology, generation of beneficial applications is a clear, stated objective. The BioBricks Foundation, a leading organisation of scientists within this field, states that: ‘When people have the tools and infrastructure to work with one another, we can meet global needs for food, medicines, shelter, clean water and air. To achieve this better future, BioBricks Foundation supports the open and ethical development of biotechnology that benefits all peoples and the planet.’37

Of course, there will not always be agreement as to what is desirable in terms of science and technological innovation. The notions of ‘public

34 In a similar fashion to Brownsword and Somsen, ibid.
35 The use of the term ‘happiness’ is inspired by Demissie’s discussion of ‘beneficence’ as a regulatory virtue. Drawing on the philosophy of Imanuelle Kant, Demissie explains that beneficence is a broader concept than ‘charity’ or ‘humanity’ because it encompasses providing for the ‘happiness’ of others as well as their basic ‘wellbeing’. See Hailemichael Teshome Demissie, ‘Justice or Beneficence: What Regulatory Virtue for Nano-Governance?’ (2011) 2(3) European Journal of Law and Technology 1, 8.
interest’ and ‘public benefit’ are highly contested. Democratic decision-making and wide public engagement in decision-making are important in such debates.38

1.4 ASSESSING SYNTHETIC BIOLOGY’S REGULATORY ENVIRONMENT

This section will explain the criteria that can be used to assess the adequacy of synthetic biology’s existing regulatory environment: regulatory legitimacy, effectiveness, prudence (which can be seen as an aspect of effectiveness), connection and cosmopolitanism.

Initially, it is necessary to consider the meaning of terms relating to ‘regulation’. In this book, I will use ‘regulation’ to refer to interventions that are put in place by regulators to ‘control and channel conduct in the desired way’.39 ‘Regulators’ are government agencies authorised to engage in such regulating activities.40 Interventions which are not put in place by agencies of government, but by industry or scientists, will be described as ‘self-regulation’. I will use the term ‘regulatory environment’ as a shorthand to mean both of these sets of interventions, including the applicable legislative regime, government regulatory institutions and voluntary mechanisms.

I will use ‘social and scientific context’ as a shorthand to indicate all the surrounding circumstances into which the regulation is introduced, including – in the case of an emerging technology – the relevant science, the regulatees and other interested parties, the nature of the industry, the relevant debates and ethical or other disagreements, uncertainties, risks and potential benefits.

1.4.1 Regulatory Legitimacy

What does it mean to create regulation that is ‘legitimate’? The concept of regulatory legitimacy has two limbs. The first is legitimacy of regulatory purpose; that is, whether regulators are doing ‘the right kind of thing’.41 This is a question of the ethical appropriateness or justifiability

---

38 As emphasised by Galligan in relation to the importance of elected decision-makers, broad consultation and public participation in biotechnology regulation generally: Galligan (n 36) 342–3.
39 Brownsword (n 16) 7.
40 See the sense in which ‘regulators’ is used in ibid.
41 Brownsword and Somsen (n 19) 11.
of the regulatory action. Secondly, legitimacy involves considering the ‘regulatory means’; are the regulators ‘going about their business in the right kind of way’? For example, a regulatory intervention that creates concerns about autonomy or privacy may not be legitimate.

Regulatory legitimacy also has a procedural element. Regulators should be able to show that they are trying in good faith to implement regulatory regimes that accord with the community’s moral commitments. Procedural legitimacy requires regulators to be transparent, accountable and inclusive. Decision-making should be done by elected representatives, and must also be well-informed and take account of all perspectives.

Public participation is an essential part of procedural legitimacy. There should be opportunities for those who are interested to express their views and decision-making should be responsive to those views. Indeed, intellectual property and emerging technology law scholar Gregory N Mandel has pointed out the importance of public trust and confidence in regulation of emerging technologies generally. He has emphasised the crucial role of broad stakeholder engagement in developing effective regulation in this context.

In the story of synthetic biology, important questions have arisen as to who should be involved in debates about the limits of synthetic biology research, its regulation and oversight. Further, to what extent should ethical and philosophical perspectives be part of the regulatory debate, along with scientific information? ‘External accountability’ is critical in this discussion. That is, synthetic biology research efforts need to be

---

42 Brownsword and Goodwin (n 15) 51.
43 Brownsword and Somsen (n 19) 11.
44 Brownsword and Goodwin (n 15) 60.
45 Roger Brownsword, Rights, Regulation and the Technological Revolution (n 16) 179.
46 Ibid., 127.
47 Brownsword and Somsen (n 19) 17–19.
48 Galligan (n 36) 342–3.
49 Brownsword and Goodwin (n 15) 48.
50 Brownsword, Rights, Regulation and the Technological Revolution (n 16) 128.
52 Joy Y Zhang et al, ‘The Transnational Governance of Synthetic Biology: Scientific Uncertainty, Cross-borderness and the “Art” of Governance’ (BIOS Working Paper No: 4, BIOS (Centre for the Study of Bioscience, Biomedicine,
accountable across all the various disciplines which make up synthetic biology, and outside science to ‘all those who may be affected’. This notion of external accountability raises particularly difficult questions where those doing the research are not ‘traditional’ scientists, but ‘backyard’ or ‘do-it-yourself’ biologists. This book will investigate the risks, benefits and oversight issues that arise from the emergence of such unique communities.

This book considers regulation of a technology at a relatively early stage in its development, when few regulatory interventions have been introduced specifically for synthetic biology. Thus procedural legitimacy is the major form of legitimacy discussed. Issues of controversy about the risks and benefits of synthetic biology, who is consulted about its regulation and who is able to influence its development are key themes in this discussion. Some see procedure as important in managing a plurality of views, for example the Chair of the Commission, Amy Gutmann, espoused an approach of democratic deliberation for bioethical issues. This book will explore the application of this approach in synthetic biology regulation.

1.4.2 Regulatory Effectiveness

Assessing regulatory effectiveness involves asking ‘whether the regulation is making a difference’; that is, whether it is ‘achieving the intended regulatory effects’. This is most helpfully seen as a matter of degree, rather than categorically defining approaches as effective or ineffective. Effectiveness is an assessment that is made when regulation is already in place; that is, the relevant standards have been set and implemented.

Assessing regulatory effectiveness raises issues such as whether enough action has been taken to address risks, whether the regulation has
Introduction

clarity, whether the regulation is being complied with, whether there is resistance from regulatees, whether regulatory overreach has occurred, and whether problematic unintended consequences of the regulation have developed.\(^{58}\) Ineffective regulation can be due to problems relating to regulators, problems relating to regulatees, and disruptive externalities.\(^{59}\)

(a) Regulator failure

The potential failures by regulators include regulatory corruption, regulatory capture and regulatory competence.\(^{60}\) Insufficient regulatory competence is the main area of regulator failure discussed in this book. This can occur where there has been inaction in addressing a new technology.\(^{61}\) For example, in relation to nanotechnology, it has been argued that the existing regulations were not sufficient due to the way materials were defined, and the regime failed to adequately take into account the different properties of materials on the nano-scale.\(^{62}\) Thus, there were significant gaps in regulation in relation to nanotechnologies.\(^{63}\) The regulators did not take sufficient proactive measures to manage the risks posed by nanomaterials.\(^{64}\)

Similar kinds of regulatory effectiveness are considered in this book in relation to synthetic biology. I have investigated whether existing regulatory mechanisms, designed for regulating earlier technologies, are rendered ineffective by their application to synthetic biology. That is, I have queried whether synthetic biology’s emergence creates gaps and deficiencies in the existing regulation. Where there are deficiencies, I have considered the questions of how these gaps ought to be filled, and whether something new and specific to synthetic biology is needed.\(^{65}\) Where I identify that new intervention is required, my aim is to identify

\(^{58}\) Ibid., 24–5; Brownsword, Rights, Regulation and the Technological Revolution (n 16) 134–45, 148–9; Brownsword and Goodwin (n 15) 290–95, 301, 312–16.

\(^{59}\) Brownsword and Somsen (n 19) 23.

\(^{60}\) Regulatory ‘corruption’ occurs when there is a lack of integrity and problems arise such as bribery, ignoring non-compliance or issuing improper permissions. The related problem of ‘regulatory capture’ arises where regulatees have ‘undue influence’ in relation to regulatory standard-setting, or monitoring and compliance: Brownsword and Goodwin (n 15) 297–300.

\(^{61}\) Ibid., 296, 301.

\(^{62}\) Ibid., 301, 313.

\(^{63}\) Ibid., 301, 315.

\(^{64}\) Ibid., 296, 301, 313–16.

\(^{65}\) Ibid., 315.
the reasons why synthetic biology necessitates a distinctive approach, and
move towards a response to the unique regulatory challenge.

(b) Unintended consequences of regulation
Regulatory effectiveness can also be diminished by unintended conse-
quences of the regulation. The unintended consequences discussed in
this book arise from intellectual property law’s interaction with emerging
technologies. The intellectual property system, in particular the patent
system, is designed to incentivise innovation. In theory, the grant of
monopoly property rights in an invention provides a reward for the
inventive effort and capital that has been expended, in turn creating an
incentive to innovate. In return for the legal monopoly, the patent
holder cannot keep their invention secret; it must be fully and publicly
disclosed (though the patent holder can charge fees for its use). Thus
the invention becomes part of general human knowledge. By creating a
reward for innovating in response to market demands, the patent system
is intended to form a ‘self-correcting innovation policy’. In this way,
the patent system is underpinned by the goal of promoting the progress
of science and technology.

Patent law is thus designed to have a facilitative role in fields such as
genetics, where the ‘working assumption’ is that the possibility of being
rewarded for innovation with a patent right creates an incentive to invest
in research. However, in some areas of technology it has been argued
that the patent system can actually impede innovation, contrary to this
facilitative role. This is an unintended negative consequence of the

66 Ibid.
67 James Boyle, The Public Domain: Enclosing the Commons of the Mind
(Yale University Press, 2008), 5–7; Hector MacQueen et al, Contemporary
68 Boyle (n 67) 6; MacQueen et al (n 67) 366.
69 Ibid.
70 Ibid., 5–8.
71 Indeed, the legislative goal for enactment of the provisions of the patent
system in the US is found in the Constitution, which grants Congress power to
‘promote the progress of science and useful arts, by securing for limited times to
authors and inventors the exclusive right to their respective writings and
discoveries’: Constitution of the United States Art I § 8.
72 Brownsword, Rights, Regulation and the Technological Revolution (n 16)
20.
73 See, e.g., in relation to synthetic biology: Arti Rai and James Boyle,
‘Synthetic Biology: Caught Between Property Rights, the Public Domain and the
regulatory intervention.\textsuperscript{74} In the context of gene patents, concern about the impact of such negative consequences on both researchers and patients has led to high-stakes litigation. In light of these issues, regulators should take an interest in how the patent system affects new technologies, both in principle and in practice.

That is, patent law should be designed, interpreted and applied in a way which facilitates rather than impedes scientific innovation. If the intellectual property system was not working in this way, but was instead hindering innovation, there would be regulatory ineffectiveness. The design or application of the patent system would need to be changed, in order to achieve its goals. These are big-ticket questions in the synthetic biology context, where huge amounts of money are being poured into research and revolutionary beneficial applications are being promised. The ownership and control of these applications will influence the trajectory of development of the field and its ability to make a positive difference in the world.

An alternative to seeking ownership of technological innovations is to share these freely with others. In the synthetic biology world, some scientists have created their own ‘commons’ for sharing of data, tools and ideas.\textsuperscript{75} These scientists value openness of scientific research, collaboration and community. The tension between ‘open’ and ‘closed’ research is pervasive in debates around synthetic biology, and is a recurring theme throughout this book. In addition to exploring the operations of this synthetic biology commons, this book will engage with the disagreement about the extent to which synthetic biology research should be open to all, particularly in the context of biosafety and biosecurity risks.

(c) Regulatee resistance
Regulatory failure can also arise where regulatees resist the regulatory intervention.\textsuperscript{76} This may be for economic reasons – such as the cost of compliance compared to the potential costs of being found in breach of obligations – or there may be cultural reasons.\textsuperscript{77} Matters of legitimacy and effectiveness can be linked.\textsuperscript{78} For example, regulatees may not

\textsuperscript{74} See Brownsword and Goodwin (n 15) 290–95.
\textsuperscript{75} See Boyle (n 67) 176–8; Sapna Kumar and Arti Rai, ‘Synthetic Biology: The Intellectual Property Puzzle’ (2007) \textit{85 Texas Law Review} 1745, 1763–7; Rai and Boyle (n 73) 0391–2.
\textsuperscript{76} Brownsword and Somsen (n 19) 24–5.
\textsuperscript{77} Brownsword, \textit{Rights, Regulation and the Technological Revolution} (n 16) 137; Brownsword and Goodwin (n 15) 318–19.
\textsuperscript{78} Brownsword and Somsen (n 19) 11.
comply with regulation because they do not view it as legitimate.\textsuperscript{79} Commentary on information technology regulation has proposed that regulation is more likely to work if regulators seek to generate consensus with stakeholders (including regulatees, such as those who might have the ability to resist regulation).\textsuperscript{80}

In a related vein, the influential ‘responsive regulation’ theory of legal academic and economist Ian Ayres and sociologist of law John Braithwaite proposes industry self-regulation as a starting point, with increasingly interventionist measures if this is not implemented.\textsuperscript{81} Under this model, regulators should seek a cooperative model in which they try to ‘persuade’ regulatees, in order to encourage effective self-regulation and compliance.\textsuperscript{82} The threat of more intrusive government action and escalating sanctions if regulated firms ‘defect’ is said to promote compliance.\textsuperscript{83}

Similarly, the theory of ‘smart regulation’ – developed by regulatory scholar Neil Gunningham, political scientist and regulatory scholar Peter Grabosky and environmental scientist and regulation specialist Darren Sinclair – proposes that ‘less interventionist’ measures should be used initially.\textsuperscript{84} The regulatory action can be escalated as needed to achieve the policy goals.\textsuperscript{85} In smart regulation, escalation can occur across multiple instruments and these instruments may be implemented by government, regulatees or third parties.\textsuperscript{86}

However, there are objections to self-regulatory approaches in terms of effectiveness and legitimacy, as regulatees may seek self-interested regulation.\textsuperscript{87} While smart regulation has worked well in environmental protection, some of its principles have ‘very limited application’ to

\textsuperscript{79} Ibid.
\textsuperscript{80} Stuart Biegel, \textit{Beyond Our Control?: Confronting the Limits of Our Legal System in the Age of Cyberspace} (The MIT Press, 2001), 221–5, 357–61.
\textsuperscript{81} Ian Ayres and John Braithwaite, \textit{Responsive Regulation: Transcending the Deregulation Debate} (Oxford University Press, 1992), 35–41.
\textsuperscript{82} Ibid., 35–51.
\textsuperscript{83} Ibid., 35–41.
\textsuperscript{85} Ibid.
\textsuperscript{86} See ibid., 399–400.
\textsuperscript{87} Brownsword, \textit{Rights, Regulation and the Technological Revolution} (n 16) 153–5.
biotechnology. Starting with less interventionist approaches would be less appropriate here, where the consequences of regulatory failure could potentially be catastrophic. Also, smart regulation assumes that there is a level of agreement on the regulatory goals, but there are often fundamental disagreements about this in the biotechnology sphere. The story of synthetic biology regulation, including attempts at self-regulation, highlights such disagreements and related challenges.

(d) Regulatory prudence
Emerging technologies create difficulties for regulation because there is uncertainty both about the risks they pose and their potential benefits. ‘Regulatory prudence’ refers to ‘prudential assessment of risk and benefit’. It involves making sure risks are at an ‘acceptable level’, which can be seen as an aspect of regulatory effectiveness.

Decisions made on the basis of an assessment of risk and benefit should be ‘provisional’ so that regulatory instruments can be modified as the technology, and public response to it, develops. Further, prudent regulators should engage with the public before taking regulatory action. Regulators need to assess public views and preferences regarding risks associated with new technologies, but this can be challenging. The considerations of democratic deliberation are therefore important here.

What approaches are then open to regulators? Regulatory strategies for emerging technologies are ‘permissive, promotional, precautionary or preventive’, depending upon their impact upon the technology. ‘Promotional’ policies increase the spread of the technology; those which slow

89 Ibid., 7.
90 Ibid., 7–8.
91 Brownsword and Goodwin (n 15) 113.
92 Ibid., 114.
93 Ibid., 316.
94 Ibid., 136.
95 Ibid., 166.
96 Ibid., 120, 136.
97 See Gutmann (n 54) 19–21; ibid., 58–9.
down the spread are ‘precautionary’, those which halt the development of the technology are ‘preventive’ and those which are neutral in relation to spread of the technology are ‘permissive’.

To choose an approach, regulators need information about the likelihood that a technology could cause harm or be abused, and possible options for preventing this. Generally, the more information there is available, the more likelihood there is of devising the ‘right kind’ of regulatory approach. However, in the case of relatively ‘immature’ technologies, such as synthetic biology, the information available is not adequate. Where there is uncertainty, such as scientific uncertainty about the likelihood of harm, the type of harm or its severity, these analyses are more complex. Thus managing scientific uncertainty is a key aspect of the challenge of responding to risk.

In relation to synthetic biology, there are novel risks and a high degree of uncertainty. Because synthetic biology falls within a category of unpredictable and still emerging technologies of which novelty is a key feature, the uncertainty surrounding the risks and benefits of the technology is pervasive. The nature and extent of potential harms, as well as their likelihood, are often unclear. As the field is progressing at a very rapid pace, the directions in which it will develop and the time frames for developments to occur are also uncertain.

Tools such as the precautionary principle have been proposed to manage scientific uncertainty. The precautionary principle can be defined as ‘a principle of public decision-making that requires decision-makers in cases where there are “threats” of environmental or health harm not to use “lack of full scientific certainty” as a reason for not taking measures to prevent such harm’. There are criticisms of the precautionary principle, some of which are valid. However, because of the substantial uncertainty surrounding synthetic biology, the principle has utility. It can be applied in ways which need not halt the development of this new field.

---

99 Ibid.
100 Brownsword and Somsen (n 19) 39–40.
101 Ibid.
102 Ibid.
104 Brownsword and Goodwin (n 15) 113, 129.
This book will explore precaution and other tools for managing uncertainty such as ‘adaptive management’ and ‘planned adaptation’.106

1.4.3 Regulatory Connection

Because modern technological development moves faster than regulatory development and uses of technology change over time, regulation can become ‘disconnected’ from the technology.107 Regulators need to be proactive about understanding the risks posed by a technology.108 They also need to foster debate regarding the ethical and social issues that arise.109

While regulators may try to incorporate flexibility to allow the regime to keep pace with technology, the goal of flexibility will always be in tension with the need for clear and consistent regulation.110 If regulatees become unsure of how regulatory instruments will apply to them, the regime becomes ineffective.111

Mandel has proposed that connection requires governance to follow an adaptive and iterative model.112 This can occur through a ‘continuing cycle’ of regulation, data gathering on the risks associated with the technology, evaluation and modification of the regime.113 In this model, Mandel recommends that regulatory agencies be proactive in addressing the gaps that new technologies can illuminate or exacerbate. In this book, I consider approaches such as planned adaptation, which can be used to promote regulatory connection in relation to the fast-changing science of synthetic biology.114


107 Brownword and Goodwin (n 15) 372.

108 Ibid.

109 Ibid.

110 Brownword and Somsen (n 19) 29.

111 Ibid; Brownword, Rights, Regulation and the Technological Revolution (n 16) 160.

112 Mandel (n 35) 83.

113 Ibid., 89.

1.4.4 Regulatory Cosmopolitanism

‘Regulatory cosmopolitanism’ refers to the challenge of developing transnational regulation in relation to emerging technologies, which may evoke differing attitudes across jurisdictions. Cosmopolitanism involves seeking to find common values across nations, but also to respecting differences. The challenge of addressing a plurality of perspectives and ethical positions across national jurisdictions is largely beyond the scope of this book. However, it is important to bear in mind the international nature of the field of synthetic biology research, the synthetic biology industry, and the regulatory issues posed. These considerations will be touched on in relation to the major risks posed by synthetic biology, particularly the risk of environmental harm and loss of biodiversity. The development of transnational regulation is a significant challenge confronting synthetic biology, and a key avenue for further investigation.

1.5 OVERVIEW OF THIS BOOK

The remaining three chapters in Part I will set the scene for the in-depth analysis of specific regulatory issues to follow. To start with, the discussion of the regulation of synthetic biology must be grounded in an understanding of the science. Chapter 2 introduces the science of synthetic biology and explores the development of the field, the leading scientists, the location and funding of research and its key applications in biofuels, medicine, agriculture and environmental remediation.

Chapter 3 analyses key policy positions in the debate over regulation of synthetic biology, represented by Venter, Endy, sociologists Joy Y Zhang, Claire Marris and Nikolas Rose, and the anti-technology civil society organisation ETC Group.

Chapter 4 considers the role and recommendations of the Presidential Commission’s inquiry into synthetic biology. The recommendations, based on the principles of ‘public beneficence’, ‘democratic deliberation’, ‘intellectual freedom and responsibility’, ‘responsible stewardship’ and ‘justice and fairness’, are critiqued.

In Part II, Chapters 5–7 consider issues of risk and uncertainty. These are pervasive in debates about synthetic biology. Chapter 5 focuses on the

---

115 Brownsword and Somsen (n 19) 11; Brownsword, Rights, Regulation and the Technological Revolution (n 16) 185–211.
116 Brownsword and Somsen (n 19) 31–2; see also Brownsword, ibid.
potential for synthetic biology to cause environmental damage. It considers strategies for managing risks to the environment in light of legal and policy approaches to regulating where there is scientific uncertainty. I critique the Commission’s approach to issues of risk and uncertainty, which is based on the principle of ‘responsible stewardship’ and the concept of ‘prudent vigilance’.

Chapter 6 examines the potential biosafety issues arising from synthetic biology. It focuses on the emerging community of do-it-yourself biologists, their culture and motivations to elucidate the regulatory challenges posed.

In Chapter 7, I examine regulatory approaches to synthetic biology’s security risks with reference to new scientific capabilities, the existing regulatory environment and self-regulation. I consider the debate that has been occurring in relation to regulation, and oversight efforts including the existing legislation, voluntary guidelines for oversight of gene synthesis, self-regulation by the synthetic biology community and voluntary standards developed by gene synthesis companies.

In Part III, Chapters 8 and 9 explore regulation for the benefits of synthetic biology, both within and outside the patent system. Chapter 8 investigates the interaction between synthetic biology and the patent system, in the context of the longstanding debate over patenting and the life sciences. The interpretation and expansion of patentable subject matter in relation to biotechnology is one of the key areas of controversy in this debate.117 The chapter considers the likelihood of patents having an unintended negative impact on innovation in synthetic biology.

Chapter 9 investigates the ability of a unique synthetic biology ‘commons’, built by the BioBricks Foundation and its collaborators, to promote innovation in the field.118 This commons involves sharing of research information and data, as well as shared norms and goals. Chapter 9 considers why this approach has been adopted by some synthetic biologists, how it is governed and how successful this project is likely to be in achieving its goals.

Together, these chapters will demonstrate that synthetic biology involves a revolutionary set of technologies that present regulatory challenges in the areas of environmental risk, biosafety, biosecurity and

118 See Boyle (n 67) 176–8; Kumar and Rai (n 75) 1763–7; Rai and Boyle (n 73) 0391–2.
Regulation of synthetic biology

intellectual property. They will highlight that the regulatory challenges posed by synthetic biology are distinctive from those posed by earlier technologies. The challenges arise from the distinctiveness of the science – including the use of engineering principles and the development of new tools – the novel communities of scientists and amateur scientists, and the uncertainty surrounding the risks. In Chapter 10, I will bring together the key regulatory changes needed and highlight critical issues for future consideration. I will consider the creation of a new institution for enhanced regulation of synthetic biology, to manage risk and promote desirable innovation.