

Chapter 8

Regulation

Chapter 8 - Regulation

Chapter overview

In this Chapter we sketch the main aims of regulation and argue that the difficult choices faced in the regulation of emerging biotechnologies are themselves examples of difficult choices made in most other important regulatory domains. Also in common with other domains, the regulation of emerging biotechnologies is framed predominantly by notions of risk of harm (in the dimensions of safety and security) and the likelihood of benefits. However, following from our conclusions in Chapter 3 that biotechnologies are characterised by radical uncertainty and that what constitutes risks and benefits has complex social dimensions (in addition to obvious physical harm) we argue that the focus on narrow conceptions of risk is inappropriate to the development of biotechnologies (as distinct from the use of biotechnology products).

A number of other characteristics of regulation, notably its national organisation, its preoccupation with national values and imperatives, its uneasy relationship with layers of extra-national regulation, its ambiguous accountabilities and its diffusion within a blurred advisory-policy-regulatory complex of governance institutions lead to the multiplication of potentially conflicting framings of biotechnology with no obvious privileged ground on which to resolve them. We identify a number of concrete problems to which this gives rise: problems of coordination and consistency, of voluntary and involuntary circumvention, and of democratic accountability.

We conclude that regulation cannot provide all the answers to securing benefits or averting harms from emerging biotechnologies, not least because emerging biotechnologies do not fit into risk-based regulatory models but require instead an approach guided by the virtue of caution which, in turn, requires a continuous and reflective engagement with broader societal interests.

Introduction

- 8.1 Regulators in the field of biotechnologies work under at least two (somewhat contradictory) pressures. On the one hand, regulation is expected to manage and mitigate the 'risks' associated with emerging biotechnologies; on the other, it is expected to do this while enabling, or even facilitating, the delivery of substantial, possibly transformative benefits. As we characterised them in Chapter 3, emerging biotechnologies present special challenges of uncertainty, ambiguity and transformative potential that are substantially settled in the case of established technologies. Emerging biotechnologies therefore often come up against regulatory conditions that are maladapted to them and that may unnecessarily inhibit certain trajectories or compound uncertainty.
- 8.2 In this Chapter we start by describing what might be called the 'dominant frame' in the regulation of emerging biotechnologies: a frame that stresses particular notions of 'risk' and that shapes regulatory language, decisions and practice. We provide examples of regulatory systems that focus particularly on 'risk' and argue that the special challenges of emerging biotechnologies show this risk-based frame to be unduly restrictive. Appropriate regulation involves both more and less than the identification and management of measurable 'risk': more because risks may be narrowly conceived; less because pursuing this focus may obscure other considerations of importance.

The purposes of regulation

- 8.3 Regulation is often understood as being animated by the aim of avoiding adverse consequences – physical, environmental, social or moral – of something that it is otherwise beneficial to do. These consequences, beneficial and adverse, are, of course, not necessarily of the same order. It is noteworthy that some biotechnologies are particularly associated with 'ethical regulation' that is not necessarily understood in terms of the protection of the interests of those directly involved (research participants, patients, consumers, the public, future generations, etc.) but goes to the public values of society more generally.⁵⁶²

⁵⁶² See, for example, the regulatory constraints imposed on human embryo research in the UK (see the 'Warnock report': Committee of Inquiry into Human Fertilisation and Embryology (1984) *Report of the committee of inquiry into human fertilisation and embryology*, available at:

Biosafety and biosecurity

- 8.4 A particularly influential set of concerns for the regulation of emerging biotechnologies has been physical and environmental harm described under the rubrics of ‘biosafety’ and ‘biosecurity’. Of course, biosafety and biosecurity are not at all unique to emerging biotechnologies but they arise with particular force here because of the key characteristics of emerging biotechnologies: the way uncertainty, ambiguity and transformative potential simultaneously produce a culture of high expectations about benefits and high trepidation about harms, and where there are profound difficulties in predicting – or, indeed, identifying – either.
- 8.5 While the terms ‘biosafety’ and ‘biosecurity’ have no universally accepted definition and their meaning varies contextually,⁵⁶³ they can be understood in the following ways:
- Biosafety relates to “the safe handling and containment of infectious microorganisms and hazardous biological materials”,⁵⁶⁴ applicable to humans, animals and the environment.
 - Biosecurity relates to securing biological materials in the context of military and national security risks, for example in relation to biological warfare or biological terrorism. More generally, biosecurity can be understood as “the protection of living organisms from harmful effects brought about by other species, especially the transmission of disease”.⁵⁶⁵
- 8.6 As a shorthand biosafety is sometimes thought of as being concerned with keeping hazardous biological materials away from people and biosecurity as being concerned with keeping people away from hazardous biological materials.⁵⁶⁶ Biotechnologies present obvious biosafety issues given that they are intended to affect biological systems and some of these systems are capable of experiencing harm, either directly or indirectly.⁵⁶⁷ However, what makes these issues particularly difficult to manage is the potential absence of a predictable, linear correlation between intervention and effect, and the uncertainty of the benefit or harm that might accrue. This is compounded as the combined effect of the special characteristics of emerging biotechnologies simultaneously create difficulties in anticipating the effect of possible regulatory designs or decisions (‘locking in’ or ‘crowding out’ a technology, for example).

http://www.hfea.gov.uk/docs/Warnock_Report_of_the_Committee_of_Inquiry_into_Human_Fertilisation_and_Embryology_1984.pdf and in Europe Case C-34/10 *Brüstle v Greenpeace eV* (CJEU 18 October 2011), available at: <http://curia.europa.eu/juris/liste.jsf?language=en&num=C-34/10#>.

⁵⁶³ For example, biosecurity could be understood as a subset of biosafety: a procedure designed to limit the possibility of pathogens being acquired for criminal purposes could be easily understood as part of basic laboratory biosafety measures for the containment of hazardous material. In turn, biosecurity has been described as becoming “the master frame for debates about threats to human, animal, and plant-based ecologies and the policies and practices developed to anticipate and mitigate risk.” Maye D, Dibden J, Higgins V and Potter C (2012) Governing biosecurity in a neoliberal world: comparative perspectives from Australia and the United Kingdom *Environment and Planning A* **44**: 150.

⁵⁶⁴ Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health (2009) *Biosafety in microbiological and biomedical laboratories: 5th edition*, available at: <http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf>, p1.

⁵⁶⁵ Lackie J (Editor) (2007) *Chambers dictionary of science and technology* (Edinburgh: Chambers), p123. However, there is no single accepted definition of the term (see: Health and Safety Executive (2007) *Final report on potential breaches of biosecurity at the Pirbright site 2007*, available at: <http://www.hse.gov.uk/news/archive/07aug/finalreport.pdf>, p10). However, it may be taken to imply both the “containment of ideas and information as well as bio-agents” (Sture JF (2010) *Dual use awareness and applied research ethics: a brief introduction to a social responsibility perspective for scientists*, available at: http://www.brad.ac.uk/bioethics/media/SSIS/Bioethics/docs/Dual_Use_and_Soc_Resp_Guidance_FINAL.pdf) as is the case, for example, with knowledge concerning the synthesis of pathogens. See: Herfst S, Osterhaus ADME and Fouchier RAM (2012) The future of research and publication on altered H5N1 viruses *Journal of Infectious Diseases* **205**: 1628-31.

⁵⁶⁶ Sture JF (2010) *Dual use awareness and applied research ethics: a brief introduction to a social responsibility perspective for scientists*, available at: http://www.brad.ac.uk/bioethics/media/SSIS/Bioethics/docs/Dual_Use_and_Soc_Resp_Guidance_FINAL.pdf, p7.

⁵⁶⁷ The objective of the Cartagena Protocol on Biosafety is to ensure an “adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity...” (Article 1). United Nations (2000) *Text of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, available at: http://treaties.un.org/doc/Treaties/2000/01/20000129%2008-44%20PM/Ch_XXVII_08_ap.pdf.

- 8.7 An example of such a risk-based regulatory system can be found in the European framework for the contained use and deliberate release of genetically modified organisms (GMOs).⁵⁶⁸ It is based primarily on risk assessment procedures relating to physical harm. Both contained use and deliberate release require specific assessment procedures to be followed before authorisation is given:⁵⁶⁹
- An assessment of contained uses should take into account issues including disease to humans, animals and plants; and deleterious effects due to the impossibility of treating (or providing a prophylaxis for) a disease. The relevant European Directive notes that “[t]he first stage in the assessment process should be to identify the harmful properties of the recipient and, where appropriate, the donor micro-organism, and any harmful properties associated with the vector or inserted material, including any alteration in the recipient’s existing properties.”⁵⁷⁰
 - An environmental risk assessment for deliberate release has the objective of identifying and evaluating “potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment”.⁵⁷¹
- 8.8 The ‘scientific’ nature of risk assessments in this area are often emphasised. For example, the UK Department for Environment, Food and Rural Affairs (Defra) notes that “[u]nder European Union (EU) legislation, GMOs, including genetically modified crops, can only be released into the environment if a science-based risk assessment shows that safety will not be compromised”;⁵⁷² the European Food Safety Authority states (EFSA) “[g]enetically modified (GM) foods can only be authorised in the European Union if they have passed a rigorous safety assessment”.⁵⁷³ Although EFSA does not actually authorise GMOs – this is done by the European Commission – it does provide what it describes as “scientific advice” through the GMO Working Panel, which is comprised of “independent scientific experts” who release assessments based on “scientific dossiers”.⁵⁷⁴

The ‘dual use’ problem

- 8.9 The term ‘dual use’ is intricately linked with the issue of biosecurity and is applied to the tangible and intangible features of a technology that enable it to be applied to both hostile and peaceful ends with no, or only minor, modifications.⁵⁷⁵ The US National Science Advisory Board for Biosecurity (NSABB)⁵⁷⁶ describes dual-use research that raises concern as “research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment or materiel.”⁵⁷⁷
- 8.10 To some extent, all technologies (for example, metallurgy, explosives, electronics, and nuclear energy) have been used for hostile purposes.⁵⁷⁸ However, some have argued that modern biomedical research is ‘dual use’ in a way that is not the case with regard to, for example,

⁵⁶⁸ ‘Contained use’ generally refers to work in research laboratories while ‘deliberate release’ refers to activities such as placing a product on the market.

⁵⁶⁹ Article 6(2) Directive 90/219/EEC on the contained use of genetically modified micro-organisms and Article 4(2) 2001/18/EC on the deliberate release into the environment of genetically modified organisms, respectively.

⁵⁷⁰ Annex III, Directive 2009/41/EC on the contained use of genetically modified micro-organisms (recast).

⁵⁷¹ Annex II, Directive 2001/18/EC.

⁵⁷² Defra (2012) *Genetic modification (GM)*, available at: <http://www.defra.gov.uk/environment/quality/gm>.

⁵⁷³ European Food Standards Agency (2012) *Genetically modified organisms*, available at: <http://www.efsa.europa.eu/en/topics/topic/gmo.htm>.

⁵⁷⁴ *Ibid.*

⁵⁷⁵ McLeish C and Nightingale P (2005) *Strengthening the Biological Weapons Convention briefing paper No 17 (second series) – effective action to strengthen the BTWC regime: the impact of dual use controls on UK science*, available at: http://www.sussex.ac.uk/Units/spru/hsp/documents/Mcleish%20pubs%20BP_17_2ndseries.pdf, p4.

⁵⁷⁶ The NSABB is a US “federal advisory committee chartered to provide advice, guidance, and leadership regarding biosecurity oversight of dual use research”. See: National Institutes of Health (2012) *About NSABB*, available at: http://oba.od.nih.gov/biosecurity/about_nsabb.html.

⁵⁷⁷ National Institutes of Health (2012) *Dual use research and dual use research of concern*, available at: http://oba.od.nih.gov/biosecurity/nsabb_faq.html#NSABB_FAQ002.

⁵⁷⁸ Meselson M (2000) Averting the hostile exploitation of biotechnology *The CBW Conventions Bulletin* 48: 16-9, p16.

nuclear materials technology, insofar as the “underlying research and technology base is available to a rapidly growing and increasingly international technical community”.⁵⁷⁹ For example, “pathogens listed by the Government as potential agents for terrorists are used in thousands of clinical and diagnostic laboratories.”⁵⁸⁰

- 8.11 Regulatory decisions made around biosecurity and dual-use research touch on a number of areas: health, security, academic freedom, international trade and scientific and technological development. A commonly discussed biosecurity concern is the possibility of limiting research on the creation of particular pathogens from scratch, or work on increasing virulence in an attempt to reduce the likelihood of the information being used by hostile non-state actors or rival states. For example, NSABB recommended in 2011 that experimental evidence relating to a highly pathogenic avian influenza virus subtype acquiring the ability to transmit via aerosols between ferrets should not be published.⁵⁸¹ In 2012, NSABB concluded that knowledge generated by the research “could conceivably be directly misused to threaten public health or national security.”⁵⁸² There are significant uncertainties on both sides in such decisions: the likely threat to national or global security is hard to quantify and the longer range health benefits of relatively early stage research are difficult to gauge.

Relevance to issues concerning emerging biotechnology

- 8.12 There are distinctive approaches in the regulation of biotechnologies (and applied biotechnology research) depending on whether their context of application is medical or non-medical, and whether their primary perceived effect is on human health or on the environment. What is more important than technical risk assessment in relation to emerging biotechnologies is to explore the meaning of the risks and levels of uncertainty. For example, there were, and remain, considerable ambiguities associated with the implementation of GM technologies, especially in relation to food crops: technically accurate risk assessments relating to acceptable levels of cross-contamination between GM and non-GM crops, or the likelihood or physical harm to human recipients of the resulting food, fail to take adequate account of the level of polarisation in societal attitudes to the technology. As a result, many conflicting – sometimes irreconcilable – value judgments applied by different parts of society are simply excluded from the formal regulatory procedures for decision making. Such exclusions can ultimately destabilise the expected technological pathway for which regulation is designed. Whether or not they do so may depend partly on how the different framings are established in society and on how judgments are amplified in the social discourse surrounding the technology. (For example, social opposition to GM crops and foods was effectively amplified; principled opposition to human embryo research has remained marginal.)
- 8.13 The (non-)introduction of GM crops into the UK is often highlighted as an example of a failure to commercialise a new technology. Much has been said in relation to synthetic biology and nanotechnology in terms of how to avoid the ‘pitfalls’ encountered by those who went through the same process with GM crops in the late 1990s and early 2000s.⁵⁸³ To some extent, these issues could have been avoided (which does not necessarily mean a different outcome would have resulted) if there had been a more sophisticated appreciation of the complex nature of the uncertainties and ambiguities associated with the technology: simply noting the safety of a technology within particular defined boundaries does not necessarily address the concerns of those objecting to its introduction if there is a fundamental disagreement about the significance

⁵⁷⁹ Stern J (2002/3) Dreaded risks and the control of biological weapons *International Security* 27: 89-123.

⁵⁸⁰ *Ibid*, p95.

⁵⁸¹ Herfst S, Osterhaus ADME and Fouchier RAM (2012) The future of research and publication on altered H5N1 viruses *Journal of Infectious Diseases* 205: 1628-31. See also Box 3.1.

⁵⁸² National Science Advisory Board for Biosecurity (2012) *Findings and recommendations: March 29-30, 2012*, available at: http://oba.od.nih.gov/oba/biosecurity/PDF/03302012_NSABB_Recommendations.pdf, p5.

⁵⁸³ See, for example: Sciencewise (2011) *Listening or explaining? Avoiding a deficit approach to public engagement in synthetic biology*, available at: <http://www.sciencewise-erc.org.uk/cms/listening-or-explaining-avoiding-a-deficit-approach-to-public-engagement-in-synthetic-biology>.

of its effects. However, despite this, the abandonment of the public dialogue on GM food in 2010 seems to indicate that these lessons have not been taken to heart by regulators.⁵⁸⁴

- 8.14 There is often no intellectually compelling way of demonstrating that one set of priorities or concerns should ‘trump’ others. A resolution depends to a great extent on a process of reflection and wide engagement in which ethical choices will often have to be confronted. Issues of risk are important, but must be dealt with as part of the construction of a shared public understanding of the uncertainties and ambiguities associated with emerging biotechnologies. We return to this below, when we consider the issue of the precautionary principle, which has been so central to technology innovation. But having recognised the multiple difficulties of regulation we first explore what a more sophisticated understanding of regulation does to the way it should function in the domain of emerging biotechnologies.

The organisation of regulatory systems

- 8.15 We understand ‘regulation’ as being the embodiment of the decisions made by regulators, both individuals who establish regulatory frameworks and institutions (legislators, etc.) and those regulatory bodies with discretionary powers to interpret and inform the rules they exist to apply.
- 8.16 Some of the most revealing evidence we received came during a discussion with a cross-section of practising regulators and experts on the institutional structure of regulation as it relates to emerging biotechnologies, with particular reference to the connections between national and international regulatory bodies.⁵⁸⁵ This identified some key features of regulatory systems that influence emerging biotechnologies.
- 8.17 First, regulation is heavily national in organisation. Conversely, the biotechnology industries are global in range, the innovation systems that underpin those industries routinely transcend national boundaries and the mechanisms for transmission of knowledge – notably in organised scientific communities – now overwhelmingly use the single universal scientific language, English. Nevertheless, regulatory authorities, and the networks in which these authorities operate, retain very distinctive national identities. This is not surprising as, despite the importance of multinational corporate actors and the increasingly global organisation of innovation systems, key institutions remain embedded in particular national territories. The most obvious example of such embedding is provided by universities, which remain culturally, politically and financially dependent on nation states.
- 8.18 Second, regulation is heavily national in preoccupations and sensibilities. One of the most important features shaping regulation of emerging biotechnology is recurrent preoccupation with its safety and ethical implications. However, the shape and content of these preoccupations varies remarkably by territory and is plainly woven around the workings of national governing systems and national cultural understandings: from some territories, such as the UK and Europe, the uncertainties surrounding GM technology have been a significant influence on the trajectory of the technology; for others, such as the US, the issue has been of marginal importance. For some territories the ethical implications of innovations in human embryonic stem cell technology appear to have created considerable barriers to research; for others (the UK included) the consequences of ethical arguments seem to have facilitated research by putting in place clear regulatory frameworks that provided legal clarity and security for researchers.⁵⁸⁶

⁵⁸⁴ See: Sciencewise (16 September 2010) *Announcement by science minister on GM public dialogue*, available at: <http://www.sciencewise-erc.org.uk/cms/food-the-use-of-genetic-modification-a-public-dialogue>, especially the letter of resignation from the steering group of Professor Brian Wynne. In a later publication, Wynne (writing with Doubleday) identified the development of a new and fragile imaginary following BBSRC’s *Crop Science review* “to a more holistic, diversely grounded, and flexible portfolio of future scientific, agricultural and social possibilities and priorities.” Doubleday R and Wynne B (2011) *Despotism and democracy in the United Kingdom: experiments in reframing citizenship*, in *Reframing rights: bioconstitutionalism in the genetic age*, Jasanoff S (Editor) (Cambridge, Massachusetts: MIT Press), p255.

⁵⁸⁵ Oral evidence from the fact-finding meeting on policy, regulation and governance, held by the Working Party, 8 July 2011.

⁵⁸⁶ It is generally understood that in the US, ethical considerations were the reason for the restriction of federal funds for stem cell research. However, in responding to our consultation, Cesagen (ESRC Centre for Economic and Social Aspects of

- 8.19 Third, while national in organisation and culture, regulation is set within multiple layers of extra-national organisation.⁵⁸⁷ A common term to describe this situation is to characterise it as 'multilevel', which it undoubtedly is in the most obvious sense. As with any multilevel system, issues of hierarchy and coordination are critical to the way regulation is practised. However, the bloodless language of multilevel regulation fails to convey the forces moving and shaping the regulatory system. One example of such a profound force makes this point clear. In the last generation the European Union has emerged as a major actor in this regulatory system, which has given rise to a whole distinct set of preoccupations and problems. Some echo national themes, some are distinctive to the organisational culture of European Union institutions and some reflect the extent to which the Union attempts to speak as a voice for collective Union interests in the economic competition which partly powers biotechnology innovation systems. This imports a number of issues into the regulation of emerging biotechnology, such as the problem of the unreasonable burden placed on innovation to advance common economic interests,⁵⁸⁸ and problems of public accountability and democratic control where administrative power is shared between technocrats and corporate interests.
- 8.20 Fourth, although populated by public institutions, the regulatory system is, in practice, a 'mixed economy' of the public and the private. In a sense all regulation is a partnership between public regulators and private actors. Even the most extreme 'command' systems require some partnership between regulator and regulated. However, in the case of emerging biotechnologies the relationship is particularly important as many of the most significant institutions in the innovation system are private corporations. Others, like university researchers, operate within the regulatory frameworks laid down by public institutions (universities, research funding institutions) or within privately negotiated frameworks of rules governing a complex array of issues ranging from scientific integrity to prudential issues of safety and security. Indeed, some of these are considered in our separate chapters on the research process (Chapter 6) and the process of commercialisation of innovation (Chapter 9). At least since the Asilomar conference on recombinant DNA in 1975 there has been recognition among researchers that taking a responsible self-organising approach in new fields of research may forestall or delay public regulation and, indeed, develop an inclusive social discourse with aspirations to make public regulation unnecessary.⁵⁸⁹

UK regulatory systems

- 8.21 The UK has, in recent years, been marked by a lack of stability and clarity in the regulation of biotechnologies, reflecting the wider instability of regulatory institutions in the UK. The importance of the national setting of regulatory institutions means that changes in the regulatory system in the UK are particularly important for one group of readers of this Report: those who work within the UK. The picture here, as elsewhere, is mixed, involving a number of government departments, and statutory and non-statutory, executive arm's length and 'expert' bodies.

Genomics) noted that they were unaware of any hard evidence "clearly showing (for example in terms of publications, or industry success) that the restrictions on federal funding in the US have necessarily hampered research in this area".

⁵⁸⁷ See, for example, the range of international agreements and organisations concerned in some way with biotechnology. For example: the World Trade Organization, the WHO, the Cartagena Protocol on Biodiversity, the UN Food and Agriculture Organization, the Trade-Related Aspects of Intellectual Property Rights Agreement, the Biological and Toxin Weapons Convention, in addition to the various biotechnology related organisations of the European Union.

⁵⁸⁸ This is illustrated by the experience of the Lisbon process. See, for example, the heavy emphasis on innovation as a means of achieving economic progress described in European Council (2000) *Presidency conclusions: Lisbon European Council – 23 and 24 March 2000*, available at: http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/ec/00100-r1.en0.htm.

⁵⁸⁹ The Asilomar conference led to guidelines on recombinant DNA technology that restarted research after a previous voluntary moratorium, although this was subsequently criticised by some for being too focused on particular dimensions of risk (such as the decision not to include ethical and legal concerns). For two brief summaries, see: Berg P and Singer M (1995) *The recombinant DNA controversy: twenty years later Proceedings of the National Academy of Sciences* **92**: 9011-3 and Berg P (2004) *Asilomar and recombinant DNA*, available at: <http://nano.z9i.com/files/Asilomar%20and%20Recombinant%20DNA.pdf>; this approach has been developed by the current 'responsible innovation' movement that has characterised self-organising initiatives such as the Responsible Nano Forum (see: <http://www.nanoandme.org/home>) and successive synthetic biology conferences.

- 8.22 Statutory regulators who work in a particular sector, such as the Human Fertilisation and Embryology Authority (HFEA, which regulates research involving human embryos and therefore holds the keys to the door of much stem cell research), have provided some stability and appreciation of issues within a particular sector, a value evidenced by support from even some of its most consistent critics in the face of current threats to its existence as an independent regulator.⁵⁹⁰ This has made it possible to introduce a measure of regulatory flexibility in this an area where technologies continue to emerge, albeit flexibility that periodically comes up against the need to amend or clarify the framework legislation.⁵⁹¹
- 8.23 Other, more broad-based and traditionally ‘administrative’ regulators – such as the UK’s Medicines and Healthcare products Regulatory Agency (MHRA), which regulates drugs and medical devices, may have less flexibility. It has been put to us in evidence that regulatory authorities in the UK tend to interpret international and European rules more restrictively than in other countries, leading to a well intentioned, but inflexible and sometimes counterproductive, regulatory environment.⁵⁹² For example, it was suggested that the UK’s capacity to produce vaccines for new strains of influenza is severely hampered by regulation that focuses on processes rather than products: it was argued that, although the seed strains for flu vaccines can be produced in a matter of weeks using genetic engineering techniques, laboratories in the UK use slower, conventional methods because the genetic modification of influenza strains for this purpose is impeded by the regulatory system, despite the products of both methods being genetically indistinguishable. On one view, this regulatory approach may inhibit the development of novel approaches (it can be understood as an example of regulatory influence helping to lock-in a sub-optimal technology); on another, the alternative of regulating products rather than processes may be more cumbersome and complex, and vulnerable to inconsistency.
- 8.24 Elsewhere the picture is even more diffused. A number of regulatory functions are exercised by groups that have grown out of advisory committees set up, *ad hoc*, to advise Government departments on specific issues: thus the Home Office Animal Procedures Committee ‘advises’ on the use of animals in research, and the Advisory Committee on Releases to the Environment ‘advises’ on GM field trials, where the power of approval is nominally retained by ministers, although, in practice, ministers tend to defer to the technically competent though democratically unaccountable committees.⁵⁹³ The lines of accountability of these bodies are often as obscure as their origins, and they may be beholden to officials rather than ministers, with their membership drawn from nominated experts rather than via open public appointments. These committees in reality often, although not always, have a mixture of advisory and licensing or regulatory functions and, although nominally offering scientific expertise, may also extend into offering public policy and ethical advice.⁵⁹⁴
- 8.25 Beyond committees that advise ministers who formally hold regulatory powers are further officially sanctioned and respected bodies. However, these bodies are not part of any formal

⁵⁹⁰ It is proposed, and powers have been secured in the Public Bodies Act 2011 (section 5 and Schedule 5), that along with a number of other ‘quangos’ the HFEA’s functions should be merged into other general regulators. This proposal comes after plans to merge the HFEA and HTA into a proposed Regulatory Authority for Tissue and Embryos were abandoned in the face of opposition in 2007 (see: Joint Committee on the Human Tissue and Embryos (Draft) Bill (2007) *Human tissue and embryos (draft) Bill*, available at: <http://www.publications.parliament.uk/pa/jt200607/jtselect/jtembryos/169/169.pdf>, at p34ff). See also the Draft Care and Support Bill, which would amend the Public Bodies Act 2011 to allow for the abolition of the HFEA and the HTA (section 75); this proposal is, however, subject to a public consultation which closed 28 September 2012, the results of which had not been published at the time of writing. See: Department of Health (11 July 2012) *Draft Care and Support Bill published*, available at: <http://www.dh.gov.uk/health/2012/07/careandsupportbill> and Department of Health (28 June 2012) *Consultation launched on fertility and human tissue regulators*, available at: <http://www.dh.gov.uk/health/2012/06/consultation-regulators>.

⁵⁹¹ As in the case of human ‘cloning’ techniques and the creation of ‘human admixed embryos’.

⁵⁹² Oral evidence from the fact-finding meeting on policy, regulation and governance, held by the Working Party, 8 July 2011.

⁵⁹³ A striking counterexample was offered by the refusal, in 2009, of the then Home Secretary Alan Johnson, to accept the advice of the Advisory Committee on the Misuse of Drugs regarding relative classification of alcohol, tobacco and illegal drugs, which, on the principle that this was treated by the Government not merely as a technical issue but one of broader social policy, might be applauded. The lie was given to the purely technical and advisory role of the SAC by the fact that this incident threw the entire SAC system into turmoil, resulting in a review by the GCSA and the development of new ‘rules of engagement’ re-reinforcing independence, tempered by responsibility (see: Government Office for Science (2012) *Principles of scientific advice to government*, available at: <http://www.bis.gov.uk/go-science/principles-of-scientific-advice-to-government>) but not before drawing in the media and external bodies like the Royal Society.

⁵⁹⁴ For the origins and accountabilities of SACs, see footnote 480.

structure of accountability, but are able to exert influence directly in relation to the field of practitioners. These include bodies like the UK Genetic Testing Network, which advises on genetic tests for use in the National Health Service, self-described public benefit organisations such as the BioBricks® Foundation, and membership bodies and trade organisations (e.g. the British In Vitro Diagnostics Association⁵⁹⁵) that produce voluntary and self-addressed standards and guidelines, alongside international organisations such as the Organisation for Economic Co-operation and Development or the World Health Organization.

Problems of the regulatory system

8.26 In arriving at a system of regulation there are always dilemmas to be confronted and trade-offs to be made. These are not unique to emerging biotechnologies. In fact they are strikingly common. What is clear is that regulation of novel biotechnologies has itself to develop and adapt to the technologies, but in a way that cannot leave those technologies unaffected. Furthermore, it is unlikely to do so in perfect step with the technology. This means that biotechnologies may emerge under pre-existing regulatory systems that are not well adapted, and may be slow to adapt to them (gene-based vaccines and the MHRA, for example), or outside them entirely. Either of these conditions may increase the uncertainty or even result in crowding out an emerging biotechnology. Since the technologies serve potentially important social aims, questions of regulatory design may therefore also raise important issues of social choice.

Problems of coordination

8.27 The search for effective coordination has been described as the search for the ‘philosopher’s stone’ of regulation.⁵⁹⁶ As this image suggests, the search has proved elusive, and emerging biotechnologies are no exception. The fundamental reason for this is that there is no intellectually coercive solution to the problem of how to coordinate the complex institutions of biotechnology regulation, which may be national, supranational, public and private. The ‘problem’ of coordination is, in essence, a dilemma: in designing or assessing regulatory institutions there is an obligation to choose between central control (with its attendant surveillance advantages but control inefficiencies) and distribution of authority (with its attendant control advantages but surveillance problems), with a potential result being oscillation under the pressure of crisis between centralisation and distribution of regulatory authority.

Problems of evasion, circumvention and involuntary rule breach

8.28 Systems of regulation are systems of surveillance and restraint. If individuals and institutions were completely compliant with both the letter and spirit of rules no institutions of regulation would be required other than those needed to formulate the rules in the first place. The very complexity of the regulatory systems governing emerging biotechnologies shows that the regulatory system is constructed on the premise that evasion (the conscious breach of rules), and circumvention (the creative avoidance of restrictions short of rule breaking), are constants in the innovation system. We do not have to imagine a world of recalcitrant rule evaders to see why surveillance is needed. Many breaches of regulation are due to the often dizzying complexity of rules and the problem of matching particular sets of rules (which must be confirmed at one moment in time) with the constant flow of new issues produced by the dynamism of the world of biotechnology research. One of the points made to us during our evidence gathering meetings, by entrepreneurs in particular, was the intimidating complexity of

⁵⁹⁵ See, for example, The British In Vitro Diagnostics Association (2008) *BIVDA code of conduct*, available at: http://www.bivda.co.uk/Portals/0/Documents/BIVDA_CoC_leaflet.pdf. Expulsion from a professional body can be a powerful regulatory measure, depending on the level of the recognition of membership and the extent to which membership or accreditation in the case of services and facilities is given a formal acknowledgment in other regulatory systems.

⁵⁹⁶ Seidman H (1975) *Politics, position, and power: the dynamics of federal organization* (New York: Oxford University Press), p190.

the regulatory landscape faced by small start-up firms, which lack the resources of, for example, the pharmaceutical giants.⁵⁹⁷

Problems of democratic accountability and public engagement

8.29 Debates about public engagement and democratic accountability in the domain of emerging biotechnologies often turn around the divergent fears and perceptions characteristic of specialist and public perspectives, exemplified by the case of GM crops and public concerns about the ethical consequences of particular innovations or particular scientific practices (such as stem cell research). This follows from something examined above: the framing of regulatory issues in terms of risk. It arises from the central features of emerging biotechnologies identified in this Report, features that arouse simultaneously popular feelings of trepidation and expectation. During discussions with UK regulators concerning the issue of public involvement, the ‘problem’ of how to manage public perceptions of innovations was raised, unsurprisingly given the experience around the prospect of introducing GM crops to the UK.⁵⁹⁸ These are only particular instances of a recurrent set of issues faced in the domain of emerging biotechnologies: how to ensure that the ‘public’ has an appropriate level of involvement with decisions about the public good, in a domain marked by powerful corporate interests, technocratic regulators who routinely use a vocabulary accessible only to the initiated, and in multinational institutions that suffer from a considerable democratic deficit.

Problems of ‘breadth’ and ‘depth’

8.30 Another dilemma is between narrowly focused regulation involving expert bodies and sector-specific regulators, and more generic regulation that may apply well-established procedures. Technology-specific regulation provides understanding and sensitivity to the situated issues, and allows constant regulatory inventiveness to adapt to uncertainty, although it requires a higher level of autonomy (and therefore raises separate questions of accountability) and can become framed by shared interests between regulators and the regulated (for example, where the regulator’s income or existence is linked to the activity of those regulated). It may also be powerless in the face of a technological trajectory that escapes its remit.⁵⁹⁹ Conversely, broader, more generic regulators may apply rules inflexibly and be less adaptive to new technologies⁶⁰⁰ but be capable of maintaining broader alignments and consistencies.

Problems of balancing ‘soft’ and ‘hard’ regulation

8.31 An almost unending problem of regulatory design is that of striking the right balance between ‘soft’ and ‘hard’ regulation: between regulation that typically relies on voluntary codes and autonomous professional institutions, and regulation that relies on law and the unique power of the state to enforce it. ‘Hard’ regulation may be more resource intensive, involving activities that may include licensing, monitoring, inspection and enforcement, but this is not necessarily the case, and in the UK there is now an expectation that the cost of regulation should be met by those regulated, who are benefitting from the service provided by regulators. To express the distinction between hard and soft regulation as this dichotomy is to see immediately that no simple choice between ‘soft’ and ‘hard’ is possible. Any conceivable system is a mixture of the two: as we noted above, in the last analysis even the most hierarchical form of command regulation depends to some degree on voluntary compliance; and effective systems of ‘soft’ regulation (such as those organised by professional bodies) depend ultimately on the ‘bite’ of some disciplinary sanctions. There is no problem of working simultaneously with hard and soft regulation. The big problem is deciding what in the case of any particular process is the most effective combination. Everything we have said above about regulation – its often multi-level character, the influence of national settings – suggests that the balance cannot be struck by

⁵⁹⁷ Oral evidence from the fact-finding meeting on intellectual property, innovation and markets, held by the Working Party, 24 June 2011.

⁵⁹⁸ Oral evidence from the fact-finding meeting on policy, regulation and governance, held by the Working Party, 8 July 2011.

⁵⁹⁹ The longitudinal regulation of human embryonic stem cells in the UK presented such a challenge in the 2000s.

⁶⁰⁰ See paragraph 8.23.

invoking a formula, but must depend on the contingencies of the particular process being regulated.

Reframing regulation in emerging biotechnology

8.32 Most important choices in regulation have the character of dilemmas: they involve choosing between alternatives neither of which is ideal. As the earlier discussion shows,⁶⁰¹ there is – when identifying appropriate regulatory approaches for biotechnologies – a tendency to concentrate on what regulation is arguably most effective at, namely the management of a particular understanding of ‘risk’. Understanding of the nature and level of risks may well help to identify a provisionally appropriate response to these dilemmas in the case of relatively well established technologies, where the technologies are embedded in stable public frames. However, it is little use in resolving them where the risks are not well characterised, and their gravity and significance are neither stable nor understood, as is the case with emerging biotechnologies. It is important, therefore, to see the shaping of regulation of emerging biotechnologies within a context of responsible innovation that involves a much broader public reflection on the ethics, acceptability and appropriateness of specific principles, practices and measures to regulate them.⁶⁰²

Reframing (pre)caution

8.33 If regulation of emerging biotechnology requires the balancing of competing, and sometimes opposing, considerations, there are several ways in which the theory and practice of regulatory design can be distorted to inhibit this. A good example of this is provided by the functioning of perhaps the most well known principle governing regulation, not only in the domain of emerging biotechnologies but in technology generally: the precautionary principle.⁶⁰³

8.34 At root, interest in approaches of this kind to regulation arises from realisations about the limits of narrow, risk-based approaches when operating under conditions of uncertainty and ambiguity. Much criticism of the regulatory use of precaution simply ignores these limits and insists that risk assessment is universally applicable.⁶⁰⁴ But no matter how inconvenient it may be, the calculation of an optimal balance between benefits and harms is not feasible under conditions of uncertainty and ambiguity.⁶⁰⁵ On the other hand, much advocacy of precaution is associated with positions on particular technologies (like bans or phase outs), which can equally ignore uncertainties and ambiguities associated with the alternative courses of action (including maintaining the *status quo*) that are available. Partly because policy discussions of the role of precaution in technology regulation have tended to be polarised, we have formulated our ‘virtue

⁶⁰¹ See paragraphs 8.7 to 8.8.

⁶⁰² ‘Responsible innovation’ is developing as a major theme within the biosciences and technology more generally but has not come to fruition despite being presaged in various places (such as the UK’s synthetic biotechnology roadmap – see paragraphs 6.33 to 6.35). See, for example, the forthcoming work commissioned by the EPSRC on this topic: Stilgoe J, Owen R and Macnaghten P (2012 – forthcoming) *An outline framework for responsible innovation*. At an EU level, the theme has been taken up under the Science in Society Programme of DG Research and Innovation (see: European Commission (2012) *Policy and strategy documents*, available at: <http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1401>) as well as by the European Group on Ethics (see the relevant papers from the meeting of 20 September 2011: European Group on Ethics (2011) *Meetings*, available at: http://ec.europa.eu/bepa/european-group-ethics/bepa-ethics/ec-international-dialogue-bioethics/meetings_en.htm).

⁶⁰³ The first statement of the precautionary principle in an international treaty may be found in the United Nations Conference on Environment and Development (1992) *Rio Declaration, Annex I*, available at: <http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm>, Principle 15; a large literature has developed around this principle and its various forms as restated in other influential documents and instruments. See also: Harding R and Fisher EC (Editors) (1999) *Perspectives on the precautionary principle* (Sydney: Federation Press); de Sadeleer N (2002) *Environmental principles: from political slogans to legal rules* (Oxford: Oxford University Press).

⁶⁰⁴ Jones JS and Von Schomberg R (Editors) (2006) *Implementing the precautionary principle: perspectives and prospects* (Cheltenham: Edward Elgar Publishing).

⁶⁰⁵ Jaeger CC, Renn O, Rosa EA and Webler T (2001) *Risk, uncertainty, and rational action* (London: Earthscan).

of caution' under a distinct but related rubric,⁶⁰⁶ as a mode of reflection that may give rise to distinct principles when applied to different circumstances.

- 8.35 The most rigorous (and commonsense) solution to both problems is to acknowledge that precaution should not be understood as a 'rule' upon which decisions may be based, like those promoted by risk assessment or rational choice theory.⁶⁰⁷ Indeed, it is a consequence of uncertainty and ambiguity that definitive rules of this kind, despite their expediency, cannot be formally applied.⁶⁰⁸ Instead, caution should be understood as a process to be undertaken when regulation is judged to be especially subject to intractable uncertainty.⁶⁰⁹ More specifically, it offers a way to help regulators learn how to respond more appropriately when operating under the conditions of uncertainty and ambiguity.⁶¹⁰ This is best achieved by 'broadening out' the process of regulatory appraisal in a variety of different ways, such as to explore and compare more extensively the contrasting implications of alternative possible innovation trajectories (including that of 'business as usual').⁶¹¹
- 8.36 In particular, then, giving effect to the principle of caution involves the comparison of a wider range of policy options than simply saying 'yes' or 'no' to a single specific proposed technology. These may include other technologies for the same purpose or other social or organisational practices that may offer similar ends.⁶¹² The range of issues considered is also broadened out, going beyond the small set of direct or immediate factors that are most readily quantified (e.g. as risks), to include potential benefits and justifications as well as the tolerability of projected possible harms,⁶¹³ including, for example, how to balance avoidance, resilience and remediation in the face of adverse impacts. The trend for increased use of public engagement by regulators can contribute positively here in identifying and clarifying various different options and perspectives concerning how precaution can be incorporated into social choice and regulatory practice⁶¹⁴ (although here, too, there is institutional learning.⁶¹⁵ for example, the design of subsequent dialogues on nanotechnology and synthetic biology appears to have learned from the experience of earlier engagements around GMOs).
- 8.37 When regulatory appraisal becomes more critical about the quality of types of knowledge about benefits and harms, a series of other qualities of emerging biotechnologies (that might otherwise be neglected in risk-based approaches) becomes relevant. This includes the extent to which the effects of different technologies, or the developmental trajectories of the technologies themselves, may be reversible or flexible in the event of unexpected outcomes.⁶¹⁶ Such qualities are not in themselves direct expressions of benefit or harm but they become relevant when the prospect of surprise is taken seriously.⁶¹⁷ Likewise, cultivating caution can foster a greater appreciation for properties like diversity: by not putting all the eggs in one basket, so to speak, innovation policy can at the same time mitigate lock-in, hedge against limitations of knowledge, and accommodate divergent interests and values.

⁶⁰⁶ See paragraphs 4.53 to 4.55.

⁶⁰⁷ Fisher L and Harding R (1999) The precautionary principle and administrative constitutionalism: the development of frameworks for applying the precautionary principle, in *Implementing the precautionary principle: perspectives and prospects*, Fisher L, and Harding R (Editors) (Cheltenham: Edward Elgar).

⁶⁰⁸ Martuzzi M and Tickner JA (Editors) (2004) *The precautionary principle: protecting public health, the environment and the future of our children*, available at: <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.177.1936&rep=rep1&type=pdf>.

⁶⁰⁹ Fisher E (2007) *Risk regulation and administrative constitutionalism* (Oxford: Hart).

⁶¹⁰ Dreyer M and Renn O (Editors) (2009) *Food safety governance: integrating science, precaution and public involvement* (Berlin: Springer).

⁶¹¹ Stirling A (2007) Risk, precaution and science: towards a more constructive policy debate *EMBO Reports* 8: 309-15.

⁶¹² Santillo D, Johnston P and Stringer R (1999) The precautionary principle in practice: a mandate for anticipatory preventative action, in *Protecting public health and the environment: implementing the precautionary principle*, Raffensperger C, and Tickner J (Editors) (Washington, DC: Island Press).

⁶¹³ O'Riordan T and Cameron J (Editors) (1994) *Interpreting the precautionary principle* (London: Earthscan).

⁶¹⁴ See Chapter 5.

⁶¹⁵ O'Riordan T, Cameron J and Jordan A (Editors) (2001) *Reinterpreting the precautionary principle* (London: Cameron May).

⁶¹⁶ Collingridge D (1983) Hedging and flexing: two ways of choosing under ignorance *Technological Forecasting and Social Change* 23: 161-72 and Raffensperger C and Myers N (Editors) (2006) *Precautionary tools for reshaping environmental policy* (Cambridge, Massachusetts: MIT Press).

⁶¹⁷ European Science and Technology Observatory (1999) *On science and precaution in the management of technological risk*, available at: <http://ftp.jrc.es/EURdoc/eur19056en.pdf>.

- 8.38 Finally, and most importantly, the virtue of caution involves a respect for the importance of undertaking all these processes under the oversight of a variety of contending social and political perspectives, where these exist.⁶¹⁸ (This relates to the various methods of public participation and inclusive deliberation we have discussed in Chapter 5.)

Reframing surveillance

- 8.39 The conviction that caution can be exercised simply through attention to issues of risk connects to a second distortion, involving the institutional design of systems of regulation. The concern with issues of risk leads to a temptation to design systems of surveillance and control that seek comprehensively to monitor all relevant activity. This temptation is particularly strong in the wake of panics about the possible consequences of particular innovations⁶¹⁹ and connects to the question of whether and how to manage public perceptions and public reporting of emerging biotechnologies. This overemphasis on surveillance is not a property of emerging biotechnology regulation alone. An overwhelming concern with comprehensive surveillance is virtually a defining character of the regulatory systems that have emerged in the UK in recent decades.⁶²⁰ It is hardly likely, therefore, that emerging biotechnologies would be an exception to this trend although, in view of our characterisation of the problem posed by emerging biotechnologies, it leaves entirely unexamined the question of whether such measures are either necessary, sufficient or in any way appropriate to meet the objectives of regulation in such contexts.

Reframing command and control

- 8.40 To those attempting to work with regulation in emerging biotechnologies and, indeed, to the outside observer, the institutional world of biotechnology regulation can look a mess: a complex patchwork of public, private, semi-public, national and supranational institutions and practices with significant duplications and gaps. The temptation to try to rationalise this into something closer to a single system of command and control is very strong, as the widespread resort to command and control as a response to regulatory failures in other domains shows.⁶²¹ But setting aside the well known limits to command and control regulation, there is a more pertinent point still: the 'mess' of emerging biotechnologies regulation is a perfectly normal state of affairs in any complex regulatory domain. Attempting to subdue it to a single hierarchical regulatory template, especially one driven by the kind of restrictive understanding of risk described above,⁶²² is to pursue an illusion.

Reframing regulatory design

- 8.41 The twin temptations of surveillance and command and control link to a fourth temptation to be avoided. The world of regulatory design is replete with summary prescriptions of how to design regulatory systems to cope with regulatory problems. Some of the most fashionable in recent years have included:

⁶¹⁸ European Environment Agency (2001) *Late lessons from early warnings: the precautionary principle 1896-2000*, available at: http://www.eea.europa.eu/publications/environmental_issue_report_2001_22.

⁶¹⁹ See, for example, the generally unfavourable response to GM crops in Europe and the extensive monitoring and control systems associated with GM crops in the European Union. This is an archetypal example and has formed the basis of a significant academic and industrial response to new technologies, wherein relevant stakeholders seek to 'learn lessons' from the GM crop debate during the 1990s, partly with the aim of avoiding such a regulatory outcome. See: Einsiedel EF and Goldenberg L (2004) Dwarfing the social? Nanotechnology lessons from the biotechnology front *Bulletin of Science, Technology & Society* **24**: 28-33; Mehta MD (2004) From biotechnology to nanotechnology: what can we learn from earlier technologies? *Bulletin of Science, Technology & Society* **24**: 34-9. More recent technological developments – such as the nascent DNA sequence synthesis industry – seem to be pushing strongly for self-regulation. See: Schmidt M and Giersch G (2011) DNA synthesis and security, in *DNA microarrays, synthesis and synthetic DNA*, Campbell MJ (Editor) (New York: Nova Science).

⁶²⁰ See: Moran M (2003) *The British regulatory state: high modernism and hyper-innovation* (Oxford: Oxford University Press).

⁶²¹ Such as financial services, following the 2007-8 crash.

⁶²² See paragraphs 8.7 to 8.8.

- ‘smart’ regulation (particularly influential in the minds of regulators and policy makers themselves);
- ‘reflexive’ regulation, denoting regulatory systems especially capable of learning from experience;
- flexible regulation; and
- ‘light touch’ regulation.

8.42 The extent to which these are just slogans in search of solutions can be seen if we perform a simple mental experiment: trying to imagine anyone designing unintelligent, unreflective, rigid and heavy-handed systems of regulation. A particular temptation lies in the identification of appropriate forms of regulation for emerging biotechnologies with ‘soft’ regulation.⁶²³ ‘Soft’ regulation relies heavily on voluntary codes of conduct, on appeals to the sense of moral obligation of the regulated, and on the willingness and capacity of the regulated independently to conform to standards. Its appeals, for example in terms of the level of burden on the regulated, are obvious. In domains characterised by high technical complexity and traditions of professional autonomy (two features important in most areas of biotechnology) in one sense all regulation is ‘soft’ in that it cannot be conducted without the cooperation of those to whom it applies. However, it would be a mistake to rely on moral obligation and willingness freely to conform as a general principle of regulatory design. Perhaps the most important example of a ‘soft’ and ‘light touch’ regulation conducted in the UK in recent years was embodied in the styles and practices governing the regulation of financial markets by the Financial Services Authority before 2007, styles and practices that – to some extent – led to the catastrophe of the financial crisis in the UK and that have produced a pronounced aversion among regulators to the ‘soft’ mode.⁶²⁴

8.43 This is not to suggest that communities engaged in biotechnology innovation are prone to practise the kinds of excesses observed in financial markets. It does suggest, however, that regulatory design is a contingent matter, dependent on particular contextual needs and demands. The design of regulatory institutions, in emerging biotechnologies or elsewhere, offers no magic cure for resolving the ‘mess’ of the regulatory world inhabited by emerging biotechnologies. The notion of intentional institutional design is, in the words of the political scientist Robert Goodin, a “myth”. It is worth quoting his cautionary account: “Typically, there is no single design or designer. There are just lots of localized attempts at partial design cutting across one another, and any sensible scheme for institutional design has to take account of that fact.”⁶²⁵

8.44 A particularly important recent example of the one-size-fits-all design illusion is provided by the regulatory (or more accurately deregulatory) policies of the Coalition Government that came to power in the UK in 2010. Whatever the arguments in favour of a policy of deregulation generally, the conditions of emerging biotechnology do not support such a single policy line. It is of the very essence of the domain that uncertainty, ambiguity and transformative potential constantly throw up unexpected regulatory challenges. To imagine that these challenges can be met by a single deregulatory rule is illusory. This is not to say that the regulatory future must involve a commitment to regulatory intervention. As we show in the next Chapter, there are instances where regulatory controls can be an obstacle to innovation and commercial exploitation.⁶²⁶ But any choice, be it regulatory or deregulatory, needs to be contingent on the particular problems raised by any particular technology.

⁶²³ See paragraph 8.31.

⁶²⁴ See: Financial Services Authority (2009) *The Turner review: a regulatory response to the global financial crisis* available at: http://www.fsa.gov.uk/pubs/other/turner_review.pdf, p86ff.

⁶²⁵ Goodin RE (1996) Institutions and their design, in *The theory of institutional design* Goodin RE (Editor) (Cambridge: Cambridge University Press), p28.

⁶²⁶ See paragraph 9.28ff.

Conclusion

- 8.45 It is rare for there to be a single ‘right’ regulatory solution, whether the ‘problem’ to be solved is a substantive regulatory issue or a problem of a feature of regulatory institutional design. That is particularly the case in domains marked, as is emerging biotechnologies, by ambiguity and uncertainty, and it happens also to be a feature, as we have emphasised above, of the nature of design theory in regulation. Regulatory decision making is a special case of a larger feature emphasised throughout this Report, namely, the way decisions constantly close down and open up ranges of options. It therefore follows that what is important in regulation is that, in closing or opening possibilities or choices there has to be, in part, a sense of the *ethical* implications of choices made.
- 8.46 In one form or other, approaches guided by caution are now embedded in the language of emerging biotechnologies regulation – rightly so, because of those defining features that have loomed large in this Report: uncertainty, ambiguity and transformative potential. However, as is clear from the discussion earlier in this Chapter, the implications of caution are not themselves without ambiguity. This simply adds weight to our advocacy of the virtue of caution: the importance of humility in the face of uncertainty and the importance of considering the widest possible range of affected interests.
- 8.47 Much of the discussion of public engagement with emerging biotechnologies is couched in the language of ‘managing’ public expectations and perceptions, particularly expectations and perceptions created and sustained by the mass media. This was noted by a number of those who submitted evidence in response to our open consultation. No doubt the engagement is important for the avoidance of manifestly distorted perceptions. However, there is a more fundamental reason for public engagement and it arises out of a key feature of the regulatory system emphasised throughout this Chapter: the regulation of the domain offers no single, intellectually compelling solutions to pressing regulatory problems. At best it offers only a range of possible solutions, typically involving hard choices between alternatives (hence, dilemmas). The critical features of such choices are that they are, at least in part, ethical in character and have to be made in an uncertain world. Public engagement is not a mechanism for the management of expectation but should be an intrinsic part of the regulatory process albeit that no effective regulatory system can simply consist of a forum for popular choice.
- 8.48 A key theme of this Chapter has been the problematic contribution of theories of institutional design to the creation of effective regulation. Most regulatory problems are dilemmas. They do not admit of technical administrative solutions but instead involve hard choices that often have significant ethical implications. In emerging biotechnologies, therefore, it is more important to focus on the ethical framework, and the framework of public engagement, than to chase particular forms of institutional design.