Summary

Introduction

1. This report falls into two parts. The first identifies features and challenges that are common among emerging biotechnologies, and develops an ethical approach for responding to these. It shows that 'emerging biotechnologies' are, in reality, a diverse collection of research programmes, forms of knowledge and techniques, although they encounter similar issues when they confront the practical conditions of research and innovation systems. On one hand, we distinguish *emerging* biotechnologies from established biotechnologies or those in later phases of development by highlighting the particular problems attached to 'emergence'. On the other hand, we distinguish emerging *bio*technologies from other emerging technologies by virtue of the particular issues of public interest they raise.

2. The second part of the report examines how these features of emerging biotechnologies generate difficulties within a number of different contexts – research, policy, regulation and business – and how responses to these, in turn, shape their emergence. It suggests how the ethical approach developed in the first part might be used to improve the integration of these contexts with each other and with otherwise excluded perspectives, in order to improve the ethical quality of biotechnology governance.

The Biotechnology wager (Chapter 1)

> Choices about how different biotechnologies are supported and governed have significant consequences for the pursuit of national priorities and meeting global challenges in healthcare, food, energy, the environment and the economy. But prospective biotechnologies will not necessarily develop along predictable paths. They emerge in a complex set of conditions and constraints, only some of which can be foreseen or controlled.

3. Biotechnologies already play a significant role in many areas fundamental to human wellbeing, including food and energy production, medicine, industry and intellectual capital. Although they have been responsible for substantial benefits, the historical impact of biotechnologies has not been uniformly positive. Nevertheless, as a society we place significant investment in prospective biotechnologies to increase future wellbeing, while at the same time providing remedies for the accumulated negative impacts of previous technologies. The 'biotechnology wager' refers to the way in which we are not only 'betting' on biotechnologies against other responses to the challenges we collectively face, such as climate change, food and energy security, but may even be depending on the success of future innovations simply to offset the costs of previous consumption and maintain current standards of welfare.

4. The 'wager' represents only one of a number of possible attitudes towards emerging biotechnologies. The full spectrum of attitudes ranges from whether biotechnologies will have substantial or only relatively minor impacts, and also whether those impacts will be ultimately beneficial or harmful. Reviewing the successive evaluations of past technologies it can be seen that conclusions about their impacts and utility are subject to change and revision throughout the lifetime of a technology and beyond.

5. We characterise the emergence of biotechnologies as a process of bringing together knowledges, practices, products and applications into productive conjunctions. This is a complex process that is poorly understood and difficult to model, even in retrospect. It is highly dependent on the development and innovation context and not merely on the quality of the underlying science. What can be learned from previous technologies is of limited assistance in predicting the evolution of emerging biotechnologies and can even be misleading, owing to problems of selection bias (the evidence we have is largely of the small number of inventions that developed successfully rather than the greater number that did not) and relevance (prospective technologies

may be significantly different from past technologies especially where the underpinning science is novel and its limitations untested).

6. Nevertheless, expectations of emerging biotechnologies still tend to be informed by implicit models formed on the basis of these selective experiences. We argue that such models tend to focus (inappropriately) on the potential power of the technologies themselves rather than the circumstances of their emergence. This focus may draw attention away from a balanced consideration of alternative approaches and opportunity costs, considerations that are of great importance at a social level. We conclude that taking a broad view of biotechnology as a matter of social choice requires consideration of a range of alternatives that are often absent in current technology governance. This conclusion informs our approach in this report as well as our more general advice that **commitments to particular technological pathways should be evaluated not only in terms of their expected future impacts but also by comparison to possible alternative pathways; this can help to illuminate obscured assumptions, constraints and mechanisms of the innovation system, and help to identify sites and opportunities for more constructive governance, prioritisation and control**.

Biotechnology promises and expectations (Chapter 2)

There is often a mismatch between our expectations of emerging biotechnologies and our experience of biotechnology emergence. Policy and governance are nevertheless strongly informed by expectations and visions of the future. This underlines the importance of focusing on the way in which emerging biotechnologies are represented in the contexts in which key decisions are made.

7. The term 'biotechnologies' covers a broad range of activities that are related through the fact that they involve the creation, manipulation or use of 'biological' components but may not otherwise share any feature in common. 'A biotechnology' may denote different kinds of thing, from broad fields of knowledge to particular products. The range of applications of biotechnology is also broad (including medicine, agriculture and food production, environment and industry) and a single 'biotechnology' may cut across many of these.

8. We briefly survey the recent history of biotechnology research in some key areas. These include:

   - cellular biotechnologies and regenerative medicine, for example: stem cells for transplant and disease modelling;
   - genetic engineering, for example: modification of agricultural crops and transgenic animals for 'pharming' and xenotransplantation;
   - pharmaceutical biotechnology, for example: recombinant proteins (such as biosynthetic insulin) and monoclonal antibodies (such as trastuzumab ('Herceptin'®) used to treat breast cancer), as well as RNA interference to regulate gene expression;
   - personalised medicine, for example: pharmacogenomics and the convergence of medicine with information and communications technology (ICT) applications;
   - synthetic biology, for example: parts-based approaches, metabolic pathway engineering, minimal genome and protocell research, and xenobiology; and
   - biological applications of nanotechnology, for example: biological machines, molecular motors, drug delivery devices and biosensors.

9. We note that emerging biotechnologies are promissory by nature and that ambition and expectations play an important role in securing the material conditions (including funding) that enable advances to be made. Analogies with other technological forms, for example information and communications technology, provide a powerful template for imagining the future development of emerging biotechnologies, not least because of convergence between biology and ICT in interdisciplinary fields such as systems biology. Their familiarity can help to inform non-specialist understanding of new and complex technical fields.

10. However, many technologies fail to fulfil their initial promise (either due to encountering a 'hard constraint' or being 'crowded out' by an alternative technology); they may remain 'submerged' for long or indefinite periods, or find wholly different applications from those originally envisaged. Of course, there are also genuinely transformative technologies that may exceed expectations or

create new markets or fields of application, and others that are not preceded by expectations because they arise unexpectedly in the context of use rather than through prior research or deliberate design.

11. We identify a cause for concern in the possibility that proposed pathways to imagined futures can become aligned with political interests, to the extent that resistance to a particular biotechnology initiative may be derided as 'anti-science'. At the same time, conditions may be created in which excessive promising can become an accepted part of the way researchers secure support for their research.

The threefold challenge of emerging biotechnologies (Chapter 3)

> Emerging biotechnologies are characterised by uncertainty, ambiguity and transformative potential. These characteristics make it difficult to arrive at a universal rational basis for commitment to particular biotechnologies, areas of biotechnology or indeed biotechnology at all, as means of pursuing social objectives. These characteristics should be explicitly recognised when commitments to biotechnology pathways are being considered.

12. We identify three characteristics that distinguish emerging biotechnologies from biotechnologies more generally.

13. The first characteristic is *uncertainty* about the range of possible outcomes from a given biotechnology or the likelihood of each coming about. Uncertainty is distinguished from quantifiable risk, where both the range of outcomes and the likelihood of their occurrence are predictable with a reasonable level of confidence. This distinction has important consequences for how decision making should be approached. Under conditions of uncertainty, emphasis shifts from the attempt to select the optimum pathway for biotechnology to fostering diversity of technological development, flexibility to move commitments among different technologies and precaution in innovation.

14. The second characteristic is *ambiguity* of meaning and value attached to the practices, products and outcomes of emerging biotechnologies. Even if the outcomes of various commitments to biotechnologies could be predicted with reasonable confidence these may still be understood and valued differently from different perspectives or in different contexts. The use of biological materials and systems may also have a different significance to different people. Finally, the generation novel objects not found in nature can disturb schemes of meaning and value, through ambiguity about how they relate to more familiar 'natural' phenomena. The assignment of any single framework of values to biotechnology decisions may therefore be socially contested.

15. The third characteristic is the *transformative potential* of emerging biotechnologies. The capacity of biotechnologies to produce profound changes in their social, commercial or physical environments, may have significant implications for shared ways of life, not only for the 'users' of those technologies but for all members of society. These are not merely technical or economic impacts but also social and ethical ones (for example, where social groups become inured to previously unwelcome practices). The potentially pervasive and irreversible nature of such transformations underscores the importance of opening up reflection about foregone pathways and opportunity costs.

16. These three characteristics create substantial difficulties in making decisions about what resources to commit to particular technological pathways or even to broad areas of research. We argue that typical responses to this tend to involve narrowing decisions around only selected aspects (such as potential for delivering economic growth), thereby failing to take account of broader concerns about the value of common social life and the public good. We draw attention to how the 'framing' of decisions in this way has consequences for the shaping both of technologies and social conditions.

Public ethics and the governance of emerging biotechnologies (Chapter 4)

Public interest in emerging biotechnologies suggests that they should be subject to a 'public ethics' rather than the protection of different individual interests. This can be put into practice as a 'public discourse ethics' through the cultivation of a number of important procedural and institutional virtues. Public discourse ethics offers a practical way of responding collectively to the threefold challenge of emerging biotechnologies through 'public' decision making, orientated by pursuit of the public good.

17. In this chapter we argue for a new 'public ethics' approach to biotechnology governance. The need for such an approach arises from the significant public interest in biotechnologies. There are several sources of this interest, some of which are common to other technologies.

18. One source lies in the potential of biotechnologies to create significant benefits and harms as a result not only of intended uses but also as a result of misuse, unintended consequences and associated uncertainties and ambiguities. These harms often occur at a public scale from which individuals cannot 'opt out' or be excluded.

19. The development – not merely the use – of biotechnologies gives rise to morally relevant considerations. Biotechnologies involve public goods (such as scientific knowledge) that are not typically provided efficiently by market mechanisms but usually require public provision. A second source of public interest therefore lies in the decision to support certain sorts of public goods and in the fair and effective use of public resources to do so.

20. A third source of interest arises from the distinctive significance that is attached to living things, whether this is because of sensitivities to religious and cultural attitudes, the extent of human interdependence with them, limitations of human understanding or control over biology, or the particularly sensitive structural and dynamic features of biological systems (and their potential for catastrophic effects).

21. A fourth source of interest is in the potential for certain technologies in use to affect social relations and to shape the conditions of common life in non-trivial ways, potentially changing the future options available to all in ways that may favour only some.

22. We emphasise that there is a positive moral value in developing biotechnologies to avoid or alleviate harms, and to increase human welfare and well being. However, this value should be applied consistently across possible alternative visions that guide public decision making. We propose three underlying values that will help to orientate the pursuit of wellbeing and avoidance of harm towards the public good rather than towards the private good of sectional interests:

    - Equity
    - Solidarity
    - Sustainability

23. In a plural society there will not be a single vision of the public good that can be applied in all circumstances. We propose that in relation to the governance of emerging biotechnologies the public good should be fostered through a 'public discourse ethics'. This takes place as an encounter between different ways of framing the biotechnology decisions in question. What characterises 'public' discourse in this sense are the qualities of *non-privacy* (not being carried out in isolation from public influence or scrutiny) and *non-partiality* (not being framed by private or sectional interests). We conclude that public discourse ethics should be encouraged through the cultivation of a number of procedural and institutional virtues. These are:

    - Openness and inclusion
    - Accountability
    - Public reasoning
    - Candour
    - Enablement
    - Caution

Public perspectives (Chapter 5)

The governance of emerging biotechnologies in accordance with public ethics involves an engagement between different values, understandings and visions. All approaches to public engagement have advantages and limitations, and while such engagement can be highly beneficial, we recognise that decisions about the conditions under which engagement takes place always involve dilemmas.

24. We discuss the meaning of 'the public' and 'publics' as distinct from those with authority to make decisions about biotechnology policy and governance. 'Public perspectives' in this sense are those held by a range of social actors. We distinguish a number of rationales for engaging public perspectives and discuss how the rationale may determine how any particular initiative comes to be evaluated. We examine how public engagement may contribute to more robust public decision making with regard to emerging biotechnologies.

25. In interdisciplinary questions of the sort with which biotechnology governance is concerned engagement beyond traditional scientific elites can act as a counterbalance to technical interests and cultures (such as a tendency to place undue weight on the pursuit of rapid advance at the expense of confidence in the robustness of knowledge).

26. We note major distinctions between methods of public engagement, drawing attention to the need to tailor the method to the specific context and the fact that all methods have both advantages and limitations. We conclude that there is no single 'best' method of public engagement and that the choice of approach will always involve dilemmas. Issues of selection and design are – and should always be acknowledged to be – conditional on underlying purposes and objectives. If the approaches used are poorly aligned with underlying objectives, the result may be poorer rather than better quality outcomes.

27. We set out a number of dilemmas that arise in public engagement. The first of these concerns the implications for 'upstream' engagement in relation to emerging biotechnologies, where both the underlying science and prospective applications are often obscure. Here the dilemma is created by an unwarranted expectation that the future can be predicted, and that the mechanisms through which it is produced are understood. The value of upstream engagement is in understanding the scope of the different values and interests at stake, and their associated aims and visions.

28. A second dilemma arises from a tension between the tendency of engagement to multiply questions and the needs of decision makers to find answers that justify particular decisions. In order to encourage understanding of plural perspectives while respecting accountability for decision making we recommend that **expert deliberation and public engagement exercises should report their conclusions not in the form of simple prescriptive findings but as properly qualified 'plural and conditional' advice**.

29. A related dilemma concerns the presumption, implicit in much evaluation of public engagement, that valuable engagement must produce outcomes that are 'useable' by decision makers. This is often in tension with allowing the freedom to deliberate widely and define key issues independently. Engagement should inform decision making without merely providing ready-made reasoning. We conclude that engagement criteria of 'policy relevance' should not be so narrow that outcomes of public engagement are considered relevant only if they answer policy makers' predefined questions.

30. A fourth dilemma concerns representativeness in public engagement and the relevance given to the views of a small number of participants compared to the vast number of individuals not involved. There are also dilemmas around selection: are the views of a socially representative group, for most of whom the issues are of little interest, more important than a group comprising those with an expressed interest? There are undoubtedly dangers in using samples as a mandate to justify decisions, but there are nevertheless benefits of deliberation and engagement that accrue to policy makers who engage with plural public perspectives.

31. There are further dilemmas that concern asymmetries of power and knowledge: for example, the extent to which public engagement has the effect (consciously or unconsciously) of itself informing the societal perspectives it aims to understand. Another difficulty arises from the obscurity of emerging biotechnologies, which means that 'bottom up' engagement rarely occurs except among already 'engaged' interests with established agendas. Commissioned 'top down' initiatives, however, typically only come about once the issues have been invested with political values. There is no simple or quick solution to raising the level of public engagement and debate concerning biotechnology issues generally. But one implication is that a range of forms and styles of public engagement are likely to be needed, including spontaneous 'uninvited' initiatives that take shape outside planned or institutional structures.

32. We consider how far markets can take the place of public engagement (as a way of signalling preferences) to the extent that both can be seen as ways of aggregating social preferences. We find (notably in Chapters 4 and 9) that while in the case of emerging biotechnologies markets can fail to allocate resources effectively to important social objectives, the value of public engagement in bringing social values into biotechnology policy and governance depends crucially on the quality of the ethical and political discourse.

33. Finally, we consider why biotechnology may be exceptional in requiring public engagement. One possible reason is the remoteness of bodies such as the research councils from traditional channels of democratic accountability. Other reasons include the long timescales involved in both the development of technologies and the realisation of their impacts and the need to enrich the limited treatment of biotechnologies in political institutions.

Research (Chapter 6)

Biotechnology research has a public dimension that entails responsibilities of candour and public reasoning. The participation of researchers in public discourse, for example, as communicators and government advisors requires them to resist pressures to inflate expectations of societal and economic impact, or to gloss over uncertainties and complexities associated with emerging biotechnologies and the innovation system.

34. We examine the role played by researchers in shaping the emergence of biotechnologies, looking both at the influences *of* researchers on the trajectories of biotechnology research, and the influences *on* researchers that govern how their influence is brought to bear. We consider two extreme views: that researchers themselves determine the direction of their research and that researchers are merely instruments in society's attempts to achieve goals through science and technology. We ask how the changing relationship between science and society may rebalance the position of researchers between these two extremes. The search for commercial returns, transnational pressures and convergence between different technologies can make the direction of research itself seem like an emergent property of the research system.

35. We find that it is surprisingly difficult to trace in detail where research in emerging biotechnologies is carried out or how it is funded. This is due, partly, to the lack of agreed terminology and to a failure to identify clearly the nature of research in emerging fields. However, it is clear that alongside universities and institutes established by charities and research councils, relevant research is also carried out by large and small firms (and possibly, also independently of recognised institutions, for example, by 'do-it-yourself' biologists). Likewise the main sources of funding for specific programmes and projects comes from government, directly and via research councils and the Technology Strategy Board, as well as via the European Union, charitable and philanthropic organisations and commercial firms.

36. Commercial firms influence national research policy to the advantage of their sectors or specific businesses, through the construction of powerful visions. We consider the applicability of roadmapping exercises to emerging biotechnologies and conclude that these should be approached with caution. The UK synthetic biotechnology roadmap, which is prudently not a technology roadmap on the model established in more predictable fields of technology, sets down an important marker for the development of responsible innovation in that field.

37. Research in biotechnologies is also strongly shaped by the visions encapsulated in 'grand challenges' and the idea, implicit in the 'biotechnology wager', that biotechnology holds a privileged power to address a range of societal challenges such as food and fuel security. To ensure that the formulation of challenges does not unduly limit social choice we recommend that, **when framing science policy through societal challenges, a 'public ethics' approach should be taken to avoid an overemphasis on technological rather than social solutions to problems with substantial social dimensions**.

38. We find that the expectations placed on researchers are compounded by the 'impact agenda' that has become established in underpinning academic research. We find that this can lead to inflationary cycles of 'overpromising' and 'overbelieving' that risk undermining public trust in science and technology, and misleading national policy, much as they have previously misled commercial investors (see Chapter 9). This is observed particularly in relation to economic impact which is consistently treated as a more direct and immediate outcome of research than evidence suggests is likely. In response to this we recommend that **public systems for the allocation of research funding should be designed to avoid encouraging researchers to overstep the bounds of their competence when assessing the impacts of their research in non-research contexts**.

39. Nevertheless, researchers themselves may exert significant influence through the ways in which they communicate their research to their peers, funders, the media and the public. However, it is easy for their communications to be distorted by popular visions or framed by unrealistic expectations. We have argued that biotechnology research has a public dimension and researchers therefore have public responsibilities. We recommend that **those engaging in public discourse should not only accept responsibility for the factual accuracy and completeness of information they present but also use their best endeavours to ensure, through their continued participation in this discourse, that it is appropriately qualified and interpreted when represented by others**.

40. Researchers have an important role as gatekeepers of knowledge but the main mechanism through which this is exercised, the peer review process, has weaknesses when applied to substantially novel and interdisciplinary research. As public figures, communicating research to a wider audience, and as advisors to governments and funding bodies, researchers have a particular responsibility to exercise self-restraint and vigilance to avoid projecting a false sense of 'scientific certainty'. On the other hand there should be more licence for researchers publicly to advocate research in terms of public good that goes beyond simple economic benefit.

41. There is a particular difficulty for policy makers in identifying sources of technical advice given that judgments about the quality of expertise is itself a matter requiring technical competence. To prevent the premature establishment of orthodoxies in fields characterised by uncertainty we recommend that **in all cases in which technical advice is sought by policy makers there should be a demonstrable attempt to avoid sole reliance on a limited range of established experts in particular fields**. Similarly, the context in which biotechnology research takes place can benefit from more interdisciplinary participation, including between the natural and social sciences, to explore the broader significance of research before disciplinary understandings become entrenched.

Research and Innovation Policy (Chapter 7)

> The emphasis on economic outcomes in research policy detracts from reflection on other important ethical values and is itself founded on insecure assumptions that require more examination. In emerging biotechnologies, policies should foster diversity of technological research while continuing support for innovation should be determined more prominently by social values rather than by market values alone.

42. In this chapter we examine the way in which research policy shapes the emergence of biotechnologies, focusing mainly on the UK and on the twenty-first century. Research policy for emerging biotechnologies does not have a single source and cannot be found in any single

document. The main places in which support for biotechnologies is decided are a small number of pharmaceutical and industrial firms, research councils, medical charities and a large number of dedicated biotechnology firms.

43. Strategic advice to government on the 'big picture' of biotechnology has declined with the winding up of a number of high level bodies created at the beginning of the century, which has reduced opportunities for broad debate and public access. At the same time government technology policy, including in the life sciences, has become increasingly framed by the single dimension of economic growth. While economic benefits are important, they are not solely important, and they risk obscuring other important values, though these are more difficult to quantify. The economic paradigm now dominates policy relevant to emerging biotechnologies in the UK, except the policy of charitable funders who continue to have a substantial role. Areas such as synthetic biology and personalised medicine become a focus for funding by virtue of estimates of the market value that they promise to deliver. Such policies, however, lack relevant evidence in support, although they conform to a number of assumptions that have become commonplace in research policy.

44. Reflections on research policy assume that states should fund research because it is a 'public good' that would be underprovided by the market. However, the real reasons states fund research are more complex, and include national security and economic growth. We find that there is a case for publicly funded research to generate knowledge so that it can be made available to all, independently of private interests, in order to defuse the dangers of 'overpromising' and 'overclaiming' that we have identified.

45. We investigate the assumption that 'Britain is good at research but poor at commercialisation'. We find that Britain is indeed good, but not exceptionally good, at research compared to its major competitors; while on the other hand it has actually been reasonably successful in commercialisation (although this success has declined in recent history). However, there is little evidence to link the relatively strong underpinning research in UK institutions with successful commercialisation by UK companies. Given the transnational organisation of research, and the multinational organisation of the biotechnology industry, only a fraction of research and development feeds into national growth. While there is certainly a need for better economic evidence in this area, we recommend that **the determination of biotechnology policy should attend explicitly to diverse perspectives and bodies of evidence rather than privileging a single, quantitative frame of evaluation (such as economic costs and benefits, or costs and benefits reduced to economic values)**; this should feed in not only to government policy but also to funding bodies and, indeed, to research institutions.

46. Another assumption in the policy literature is that biotechnology is central to social and economic transformation and should be supported, drawing on an implicitly linear model of technical change. However, such assumptions lack the support of reliable correlations between innovation and social and economic outcomes, and fail to take into account the complexity of real-world innovation systems. We find that the difficulties facing the pharmaceutical industry and lack of returns on its investment in biotechnology over thirty years give grounds for greater caution. We recommend that **there is a need for serious evaluation and assessment of past research policies, both of Government as a whole and of particular public funding bodies, to understand in what conditions, if any, selective approaches to support for biotechnology are plausible**. We find that selective approaches in research policy are likely to be fruitful only in very unusual conditions and, as a way of hedging against uncertainty, recommend that **policy makers should consider adopting an approach to social objectives that fosters diversity of research approaches, not just within the particular domains of individual funding bodies but across physical and life sciences, and the social sciences, combined with selective conditions of innovation that involve social benefit rather than just market value**.

47. We examine the assumption that detailed priorities in basic research are set by researchers under a general strategic steer from government (loosely referred to as the 'Haldane principle') and find that the issue of who controls UK research policy is far from clear, although business and industry figures occupy prominent places in the key decision making bodies (advisory bodies such as the Technology Strategy Board, and the research councils). We take note of initiatives to include and even institutionalise broader societal perspectives in research strategy but find there is a persistent asymmetry of influence. We therefore recommend that **research policy should**

be framed not by received assumptions but through continuous engagement with a broad range of societal interests and with the involvement of social actors who can bring understanding of these interests to the joint enterprise of constructing a public frame for research policy decisions.

48. To increase coordination and diversity of government support for research across disciplines, and to encourage the pursuit of public good that is not identified solely with economic performance, we recommend that **consideration should be given to bringing Government research policy and funding bodies under a senior minister (i.e. of Cabinet rank) free from departmental responsibilities to ensure that research properly reflects all the objectives of Government, rather than those of a particular department**. Furthermore, in order to increase openness about the way in which policy relates to social values, we recommend that **there should be a clearly defined, written and published Governmental research policy against which detailed elements of departmental and other public research policies (such as the approach and methods of funding bodies) may be assessed**, and that this should not be produced, as it was formerly, by the Treasury.

Regulation (Chapter 8)

Established regulatory systems may be maladapted to emerging biotechnologies, and the anticipation of downstream regulatory constraints may exert a negative selective pressure on them. Regulating emerging biotechnologies for the public good is not a matter of better regulatory design but requires reflection, engagement and adaptation to mitigate against undesirable crowding out or locking in of biotechnologies.

49. We sketch the main aims of regulation and note that these typically require striking a balance between enabling benefits and managing risks. We note that 'biosafety' and 'biosecurity' are particular concerns within the regulation of biotechnologies. We note that biotechnologies may be particularly susceptible to 'dual use' (i.e. being used for malign as well as benign purposes) in comparison to other technologies, as it is often the conditions of their use rather than any further technical adaptation that renders them potentially harmful. Furthermore, given the characteristic uncertainty associated with emerging biotechnologies and the fact 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 emerging biotechnologies.

50. We identify a number of tensions within the design of regulatory systems. While biotechnology innovation is global in range, regulatory culture tends to be national in organisation and national in its preoccupations and sensibilities (for example in relation to its attitude to the ethical permissibility of certain practices). However, it has to function in a supranational multilevel system, which creates tensions and problems of accountability and control. Finally, especially in emerging fields, it is often dependent on private institutions and compliance.

51. The regulatory landscape that emerging biotechnologies must negotiate is a patchwork of largely ad hoc institutions. Some are established with statutory functions which makes them inflexible when it comes to accommodating novelty; others, particularly those that have grown out of advisory committees in response to emerging biotechnologies in the past, may have undergone mission creep from advice to regulation, and from scientific to social and ethical advice, but are frequently ill-equipped to provide public-level regulation or to create a site for engagement between a full range of perspectives.

52. The design of regulatory systems faces a number of dilemmas and trade-offs, for example between centralisation of surveillance and localised control; between adequate detail and over-complexity; between faithful administration and responding to evolving social perspectives; between consistency across a broad range of activities and meeting the needs of a specific sector; and between trust and prescriptivism, backed by enforcement.

53. We suggest that the resolution of regulatory dilemmas can be inhibited by over-attachment to certain features and principles of regulatory design, including inappropriate application of the

precautionary principle to the single dimension of risk management, overemphasis on surveillance, over-intrusive regulation and 'soft' regulation. We conclude that regulatory design cannot provide all the answers to securing benefits or averting harms from emerging biotechnologies, not least because emerging biotechnologies do not fit easily into risk-based regulatory models but require instead an approach guided by caution which, in turn, requires a continuous and reflective engagement with broader societal interests.

Commercialisation (Chapter 9)

Markets often fail as effective mechanisms for organising resources in order to fulfil social objectives. In addition to the selection of the most promising and desirable biotechnologies by political, industrial and scientific elites, and leaving commercial competition to determine which innovators and innovations survive in the marketplace, social values can play a role in the shaping and selection of future biotechnologies. One approach could involve the state influencing commercial innovation by directly rewarding the public goods produced by commercial firms in accordance with social priorities determined through public discourse ethics.

54. We review the challenges faced in commercialising emerging biotechnologies, given the peculiarly long development phase and uncertain outcomes associated with them, and consider the effectiveness with which the market mechanism organises resources for biotechnology innovation to produce outcomes of social value.

55. The prospect of gain from biotech 'spin-outs' for academics and their institutions has brought commercial values directly into the publicly-funded research sector. Meanwhile, in the currently most commercialised sector, pharmaceuticals, a disappointing flow of new drugs has merely intensified the pressure on researchers to make their activities profitable. One result of this has been to rely more on academic centres and small specialised firms to carry out the most uncertain work.

56. If the most valuable activity in biotechnology is the production of knowledge, commercialising such knowledge relies substantially on the patent system. This gives the owners of the knowledge the exclusive opportunity to exploit it commercially for a defined term. It is the expectation of profits from this exploitation that provides the main incentive to innovate. We review the use and operation of the patent system for biotechnologies (specifically in the pharmaceutical sector) and find that the patent system has two principal shortcomings. First, the term of patent protection may be too *short* to allow innovators in emerging biotechnologies fully to recover, from their successful products, the costs of developing them (and offsetting the costs of those that failed). Secondly, patents in emerging biotechnologies have a tendency to provide over-*broad* protection, potentially stifling competing research and innovation.

57. Economic analysis of the pharmaceutical sector reveals a further problem with potentially more widespread implications. Patent protection allows an innovator to charge a price well above the marginal cost of production and distribution. But this price will make it inaccessible to many who would benefit, while at the same time failing to capture for the innovator all the potential social value of the product. Biopharmaceuticals, which may offer significant benefits, but only to a limited population of patients, are perhaps most affected. The entry of 'me-too' followers into the market further reduces the profit accruing to the innovator and thus the incentive for radical biopharma innovations.

58. We consider the extent to which the experience of the pharmaceutical industry can be generalised to other biotechnology sectors. We conclude that market failures are most concentrated in highly research-intensive biotechnologies with applications in open biological systems, such as pharmaceuticals and plant breeding. Biomanufacturing technologies (e.g. manufacturing processes for fuels or materials) suffer from a different kind of market failure, namely the under-pricing of alternative incumbent technologies in relation to their true social costs (such as higher greenhouse gas emissions from fossil fuels than biotechnological alternatives).

59. We consider ways of alleviating any restrictive effects of patenting on innovation. These include the use of compulsory licensing, 'open source' licensing, or the designation of research as 'pre-competitive'. Collaborative efforts (including crowdsourcing) also offer strategies to accelerate

research. For example, collaborative validation of potential therapeutic targets for new drugs and the identification of commonly acceptable surrogate endpoints (e.g. using biomarkers) to reduce the time and expense required to satisfy regulatory requirements. Biotechnologies may also benefit from very general incentives such as 'patent box' initiatives (that reward innovation through a reduction on corporation tax for products based on qualifying patents).

60. What none of these approaches achieves, however, is a reward for innovation that is directly linked to the social value of the innovation. Corporate social responsibility measures may play a role in encouraging firms to pursue socially valuable innovation and we recommend that **innovation should be included in corporate social responsibility reports as a separate, specific issue**. The development of QALYs for use in NHS drug purchasing guidance in the UK, and the move to value based pricing of drugs, are measures that are designed to bring price into line with social value. However, the persistence of the price mechanism still requires the innovator to recover their reward for innovation as a multiplication of price by the quantity of the product sold. As a radical alternative, we recommend that **consideration should be given to state interventions in the market for new biotechnologies to secure the social benefits of innovation through direct reward for socially valued innovations**. In particular, further attention should be given to schemes that directly reward the positive social impact of innovation and penalise (via taxation) incumbent technologies that have a negative impact in order to incentivise socially desirable technology change.

61. A specific mechanism for separating the reward for innovation and reward for production is discussed. Under this mechanism the price paid for a product would be set at a sufficient level just to incentivise production. Innovators would then be rewarded separately through an appropriately designed impact payment scheme. We note how, in the UK, health service structures are well suited to the determination of impact in terms of health outcomes; public discourse ethics provides a process through which the social value of these outcomes could be understood.

62. We consider how a social impact approach of this sort could be broadened beyond biomedicine to other biotechnologies that intervene in natural biological systems (for example, to plant breeding) and beyond the UK. We find that, in biomanufacturing, impact payments are unnecessary and inappropriate: here the necessary incentives will be provided by steering of the market mechanism through, for example, ecotaxation. However, here, too, there is a role for public ethics to understand how commercial incentives should be aligned with public good.

Conclusions and recommendations (Chapter 10)

63. The conclusion extracts the main argument that has been developed in the course of the report in support of a 'public ethics' of the kind that is proposed in Chapter 4. The recommendations are then related to the conclusions that are reached in specific contexts and to the virtues that underpin our ethical approach. Thus, whereas this summary has provided an overview of what the reader will find in the report, the conclusion shows where the arguments contained in the report have led.