

**Emerging
biotechnologies:**
technology, choice
and the public good
a guide to the report

NUFFIELD
COUNCIL ON
BIOETHICS

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Introduction

This guide summarises the main themes and conclusions contained in the Nuffield Council on Bioethics' report *Emerging biotechnologies: technology, choice and the public good* (published December 2012).

Notes in square brackets refer to the chapters in the report.

Biotechnologies are significant in many aspects of life including food, energy, medicine, and business; they therefore present some of the most important sources of transformation and disruption in the world today.

In practice, only a fraction of the biotechnologies that are possible can ever be developed. Those that are prioritised depend not only on the societal benefits they are expected to deliver, but also on chance, circumstance and the influence of vested interests and power.

This report is intended to stimulate thinking in a variety of contexts in which the conditions that influence the development of biotechnologies are set (research, policy, regulation and business), and about how those contexts interact. It falls broadly into two parts:

- **Part 1** identifies and examines common features of emerging biotechnologies, and develops an ethical approach to understanding and responding to these.
- **Part 2** examines how these features of emerging biotechnologies generate difficulties within the different contexts of research, policy, regulation and business that in turn shape their emergence. It suggests ways in which the ethical approach developed in the first part might facilitate and guide the interaction of these contexts in order to improve the ethical quality of biotechnology governance.

The report was produced by an interdisciplinary expert Working Party and focuses mainly on the UK environment. In reaching its conclusions, the Working Party consulted a wide range of people, including members of the public and those involved in research, public engagement, business and markets, policy, regulation and governance relevant to emerging biotechnologies.



What is an ‘emerging biotechnology’?

Emerging biotechnologies differ considerably in nature and purpose, but some common features in the way they evolve can be identified.

The term ‘biotechnology’ is used to apply to many different kinds of thing, including the following:

- a broad field of knowledge (such as synthetic biology);
- a programme of research (such as genetic modification of crops);
- a specific technique (such as DNA sequencing);
- an application of a technique (such as in vitro fertilisation);
- a product (such as a nanoscale biosensor device).

We characterise the emergence of a biotechnology as a process of bringing together knowledge, practices, products and applications into viable and productive relationships. The types of technologies that are considered in the report all involve the use, modification or creation of a biological system or process.

- Emerging biotechnologies are unlike established biotechnologies in that they are particularly sensitive to contextual factors that can shape their evolution, including those that can ‘lock in’ or ‘crowd out’ certain possibilities.
- Emerging biotechnologies are distinguished from other emerging technologies by the fact that they utilise or affect living things, and therefore engage the public interest in distinctive ways.



Examples of key areas in which significant advances are currently taking place include:

- cellular biotechnologies, including regenerative medicine;
- molecular biotechnologies, including transgenic plants and animals, and pharmaceutical biotechnology;
- genomic medicine, including personalised medicine, gene therapy and bioinformatics;
- synthetic biology, including novel engineered machines and organisms;
- nanotechnologies and nanomedicine [Chapter 2].

The biotechnology wager

Much is at stake in the decisions that are made about emerging biotechnologies. 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.

There is a prevalent belief in the potential of biotechnologies to offer limitless progress and advances for human welfare, and to overcome the negative impacts that have come about as a result of previous technologies (such as environmental damage and antibiotic resistance). This drives considerable financial and political investment.

The biotechnology wager refers to the way in which, as a society, we are not only 'betting' on biotechnologies against other responses to the challenges we face, such as climate change, food and energy security, but may even be depending on future innovations to offset the costs of previous consumption and maintain current living standards.

When we look back at the origins of technologies in the past we often fail to recognise how unlikely it may have been that circumstances should come together to produce the outcomes we enjoy today. The emergence of biotechnologies is subject to multiple conditions, including funding, regulation, economic conditions, political climate and institutional agendas, the limits of knowledge and the constraints of nature, only some of which are subject to deliberate control.

In this complex environment, commitment to certain biotechnology pathways can result in others being crowded out without effective consideration of all the available options.

We conclude

Commitments to particular technology pathways should be evaluated not only in terms of their anticipated impacts but also by comparison to possible alternative pathways [Chapter 1].



Biotechnology promises and expectations

Policy and governance of emerging biotechnologies is strongly informed by visions of the future.

Expectations about emerging biotechnologies may be formed and changed by events, ideas, political influences and past experiences. However, experience of biotechnologies is often drawn from only a few successful examples, leading to an 'optimism bias' for prospective technologies.

There are concerns that over-stated claims about the possible benefits (or harms) of a biotechnology and the timescales for innovation have become routine assumptions within policy and governance. Yet, most new technologies do not meet prior expectations, more will fail than will succeed, and those that ultimately succeed may do so in a very different form from that originally envisaged.

A critical and reflective approach to claims concerning prospective biotechnologies is therefore needed. This is not to undermine support for biotechnology research and development in general, but rather to make it stronger by looking more carefully at what the relevant evidence can support, and to encourage responsible innovation. In particular, it may help to avoid the dangers of:

- prematurely linking the development of biotechnologies to particular social objectives and thereby ignoring other potential benefits and reasons to promote the development of those biotechnologies;
- linking social objectives to particular biotechnologies and thereby failing to adequately consider and explore alternative ways of meeting those objectives [Chapter 2].



The threefold challenge of emerging biotechnologies

Three particular characteristics of emerging biotechnologies present challenges for policy and governance: uncertainty, ambiguity and transformative potential.

Uncertainty

A lack of knowledge about the range of possible outcomes of a biotechnology, for example whether desired outcomes can be achieved or unintended harms can be avoided, 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).

Ambiguity

The implications and products of biotechnologies mean different things to different people and in different contexts, and may be valued in different ways. An appreciation of the different meanings of 'harm' and 'benefit', for example, as well as whose 'harms' and 'benefits' are allowed to count and how these are distributed, may be an important condition of ethical decision making.

Transformative potential

Emerging biotechnologies have the potential to change common ways of life and open up entirely new ranges of possibilities. Transformative effects may operate not only at the level of what can be made or done, but also affect the way in which the future may be thought about or imagined.

The way in which questions of governance are framed may have a significant effect on the conditions that select and shape the biotechnologies that result. 'Framing' is necessarily partial and may distort or exclude some perspectives on meaning and value.

When commitments to technological pathways are being considered, it is important that these characteristics of biotechnologies should be explicitly recognised, and appropriate caution should be exercised [Chapter 3].



Public ethics and the governance of emerging biotechnologies

There is a significant public interest in emerging biotechnologies. Governance should be guided by a 'public ethics' approach.

The public interest in emerging biotechnologies arises from a number of potential sources, including:

- their potential to give rise to benefits and harms at a public scale;
- the public resources invested in them;
- the significance attached to living things;
- their potential to transform the conditions and horizons of common life in ways that may benefit some people at the expense of others.

We therefore suggest that development and innovation should be guided by public ethics, i.e. based on the public good, taking into account broad social contexts, circumstances, implications and alternatives rather than focussing narrowly on the impacts on individuals or on specific implications such as economic development.

Values of public ethics

We recognise that there is a positive moral value in developing biotechnologies to avoid or alleviate harms, and to increase human welfare and well being. This consideration should be applied consistently across possible alternative visions guiding public decision making by reference to three underlying values:

Equity - equal respect for the rights, interests and preferences of others, including in questions of fair and just distribution of expected benefits and costs.

Solidarity - avoiding social divisions and exploitation, and actively promoting the welfare of all those who are less advantaged, including bearing costs of research and knowledge gathering on behalf of others.

Sustainability - avoiding significant or irreversible depletion of non-renewable natural resources or damage to ecosystems or the environment [Chapter 4].

Public ethics and public discourse ethics

A public ethics approach means that, given the public interest in biotechnologies, decisions that shape and constrain the development of emerging biotechnologies should be framed by a publicly established response to uncertainty and ambiguity rather than a private one dominated by particular interests or disciplines.

Applying public ethics to the governance of emerging biotechnologies does not mean that all the conditions that affect emergence should be set by the public, or in public, or that research and development should only take place in the public sector.

What we propose is a 'public discourse ethics' as a way of establishing the context for public decisions (and for evaluating them) in accordance with the public good.

Procedural virtues

We identify a number of virtues to foster a public discourse ethics and their implications in practice:

Openness and inclusion - members of society should have the information required and, where appropriate, access to participate in biotechnological governance.

Accountability - there should be explicit acceptance and acknowledgement of where responsibility for governance lies and how it might legitimately and democratically be influenced.

Public reasoning - reasoning should be clear, explicit and aimed at finding common ground rather than promoting sectional interests, including in the presentation of evidence.

Candour - uncertainties associated with emerging biotechnologies should be represented truthfully and in good faith.

Enablement - appraisal of emerging biotechnologies should highlight alternative social and technological choices and the implications of each, and encourage wider political debate.

Caution - the degree of uncertainty and ambiguity associated with emerging biotechnologies should mean there is a responsibility to gather more extensive knowledge prior to making policy commitments [Chapter 4].

Public perspectives

Engagement with non-specialist groups has an important role to play in developing policy for emerging biotechnologies.

No single individual or community can have relevant expertise in all the areas that are relevant to decisions about emerging biotechnologies. All decisions therefore involve an engagement between different perspectives and interests. Engaging public perspectives about new biotechnologies can contribute to a more ethically robust public decision making process.

How 'the public' is constituted in relation to a question of biotechnology, and how participants in public engagement are informed (bearing in mind the role of popular or sectional media perspectives), can have a significant bearing on how opinions are formed.

There are many different approaches to public engagement. Each has their own advantages and limitations, and different methods will be needed in the many different circumstances in which public engagement is undertaken. But decisions about the conditions under which engagement takes place always involve dilemmas. We identify a number of these dilemmas, including:

- upstream v. downstream engagement
- deliberation v. decisiveness
- freedom to identify issues v. policy relevance
- representativeness v. interestedness
- informing v. eliciting
- top-down v. bottom-up
- commissioning research v. involving civil society groups



We conclude

- Public engagement can be an important way of helping ensure that social, as well as commercial, values are brought to bear in considering policies relating to emerging biotechnologies.
- Expert deliberation and public engagement exercises alike should report their conclusions not in the form of simple prescriptive findings but as conditional advice [Chapter 5].

Research

Researchers of emerging biotechnologies are subject to many pressures and influences but are themselves influential in shaping the direction of research.

Influences on researchers

A major influence on the direction of research in emerging biotechnologies is pressure from research funders, whether public, commercial or charitable. Other influences include the need to address societal challenges, the 'impact agenda' prevalent in university funding systems, visions expressed in technology 'roadmaps', and public expectations.

We conclude

- When framing research policy through societal challenges, a 'public ethics' approach should be taken to avoid overemphasis on technological rather than social solutions to problems with substantial social dimensions.
- 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.

Influences of researchers

When communicating the results of their work and hopes about where it may lead, researchers can create expectations that inform the decisions of policy makers and investors.

Through peer review, researchers can influence what research is published, where, and how important it is judged to be, as well as what research proposals receive funding. Influence on funding systems may also be possible through involvement in advisory committees that guide strategic directions of funders.

We conclude

- Researchers who take part in public discussion of research should take responsibility for the accuracy and completeness of the information they present, and should also strive to ensure that others represent the issues fully and correctly.
- When seeking technical advice, policy makers should make a demonstrable attempt to avoid sole reliance on a limited number of established experts in particular fields [Chapter 6].

Research and innovation policy

Research policy for emerging biotechnologies should take account of wider social values and not merely economic benefit.

Framing research policy

Owing to the novelty and complexity of innovation systems for emerging biotechnologies, research policy lacks a relevant, reliable basis in evidence. This deficit tends to be made up by assumptions, which are rarely examined in detail. We identify a number of assumptions that are common in the framing of UK research policy:

- a) The UK has an exceptionally strong science base in the life sciences;
- b) The UK pharmaceutical industry is extremely economically valuable to the UK;
- c) (a) and (b) are linked in that the research base powers the successful industry and the successful industry ensures the applicability of research;
- d) Biotechnology is becoming increasingly important to the pharmaceutical industry;
- e) Some areas of new science (e.g. synthetic biology) have the potential to boost other areas of UK science such as chemical and agricultural biotechnology;
- f) Public spending on research is justifiable only where there is potential to generate economic growth in Britain.

Public investment in emerging biotechnologies is increasingly justified by poorly supported claims about their expected economic impact, which tend to marginalise other important values.

We conclude

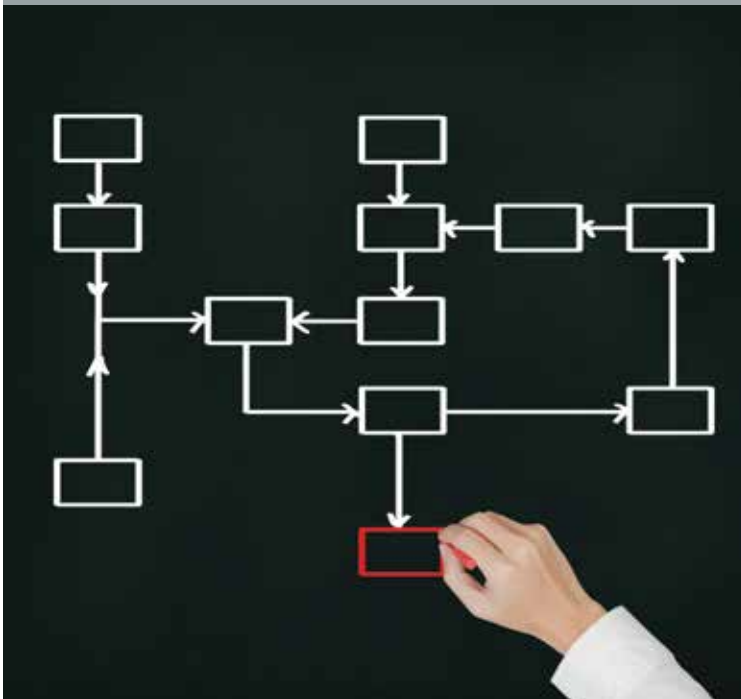
- Biotechnology policy should attend explicitly to diverse perspectives and bodies of evidence rather than privileging a single, quantitative form of evaluation (such as economic costs and benefits).
- There is a need for a serious evaluation and assessment of past research policies, both of Government as a whole and of particular public funding bodies, to understand in what conditions, if any, selective approaches to research have been effective.
- Policy makers should approach social objectives in a way that fosters diversity of research approaches across the physical and social sciences, combined with conditions of selection that involve social benefit rather than just market value.
- Research policy should not be framed by received assumptions but through continuous engagement with broad perspectives.

Policy coordination

There is no single source of policy for publicly funded research and the principles upon which it is based are not clearly defined. Without clear principles, there is a danger that research policy is determined through closed engagement between scientific, political and industry elites, with no assurance that there is adequate consideration of important social values.

We conclude

- There should be a clearly defined, written and published Governmental research policy against which public research policies (e.g. those of Government departments and funding bodies) can be assessed.
- Consideration should be given to bringing Government research policy and funding bodies under a senior minister free from departmental responsibilities [Chapter 7].



Regulation

Emerging biotechnologies require a regulatory approach that shows commitment to the broad interests of society.

As with many technologies, the regulation of emerging biotechnologies is often led by concepts of risk and harm (including safety and security) and the likelihood of benefits.

However, as emerging biotechnologies are characterised by uncertainty and ambiguity (see page 5), the risks and benefits associated with them are hard to determine or agree. Risk-benefit models of regulation are therefore not appropriate to emerging biotechnologies.

Organisation of regulatory systems

We identify some key features of regulatory systems that influence emerging biotechnologies and give rise to problems of control, coordination, evasion and accountability:

- **National organisation** - while biotechnology innovation is a global enterprise, the organisation of regulation and key institutions remains embedded in particular countries. For example, universities remain culturally, politically and financially dependent on nation states.
- **National preoccupations** - each country has their own attitudes and laws regarding safety and ethical permissibility. For example, genetically modified crops are widely accepted in some countries but have been rejected by others.
- **Extra-national organisation** - regulation is set within multiple layers of international organisation. For example, the European Union has a strong influence on the development of regulation for emerging biotechnologies in the UK.
- **Public and private co-operation** - regulation requires a partnership between public regulators and private institutions. This is especially important in regulation of emerging biotechnologies where many leaders of innovation are private corporations [Chapter 8].

The solution to the challenges they present is not to be found in the design of regulatory systems. Regulatory design will always involve dilemmas (such as between surveillance and control, consistency and precision, 'soft' and 'hard' regulation). Instead, there is a need for continuous broad reflection, engagement and adaptation to mitigate against undesirable crowding out or locking in.

Commercialisation

Commercialisation of emerging biotechnologies faces particular challenges due to the long development phase and uncertain outcomes.

Intellectual property

The main activity in biotechnology development is the production of knowledge. The commercialisation of that knowledge depends upon having a system for protecting intellectual property, the most important element of which is the patent system. However, patenting has two main failings in relation to emerging biotechnologies:

- The 20 year term of most biotechnology patents is likely to be too short to recoup investments, since most (if not all) of that time will often have passed before the technologies can be brought to market.
- Patents for emerging biotechnologies can be very broad, thus discouraging research that will lead to products that may fall within the scope of the patent and therefore require a licence.

Promoting the social value of innovation

A more fundamental problem is that the patent protection of knowledge, together with market pricing, restricts access to the fruits of research, and creates a pattern of incentives and rewards that does not reflect the social value of innovation.

We conclude

- Consideration should be given to state interventions in the market for new biotechnologies to secure the social benefits of innovation by directly rewarding socially valuable innovations.
- Innovation should be included in corporate social responsibility reports as a separate, specific issue [Chapter 9].





Summary

Biotechnologies are significant in many aspects of life, from food and fuel security, to medicine, industry, and economic development. At global and local levels, societies are committed to securing advances in biotechnology, often with high expectations about impacts that such technologies can deliver for future wellbeing.

However, the emergence of biotechnologies is a complex, undefined process, influenced by a number of competing interests, values, constraints and drivers that change over time. The uncertainty, ambiguity and transformative potential of emerging biotechnologies make it difficult to predict definitive outcomes in the early stages of research. It is therefore difficult to find a rational basis on which to commit to particular pathways of biotechnology development, which may be at the expense of other technological or social solutions.

This report sets out a 'public ethics' approach to addressing the challenges that arise in a number of contexts that shape the emergence of biotechnologies:

- Research
- Policy
- Regulation
- Business

Using this ethical approach, conclusions are reached about how to approach policy and practice, with the aim of maximising socially beneficial and democratically accountable governance of emerging biotechnologies.

Copies of the report and this guide are available to download or order from the Council's website: www.nuffieldbioethics.org

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