NUFFIELD COUNCIL ON BIOETHICS

Emerging biotechnologies

CONSULTATION PAPER

April 2011

How to respond

Please respond by the 15th June 2011.

If you wish to respond electronically please email your response, with a copy of the response form (which is available at www.nuffieldbioethics.org/biotechnologies), to:

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If you wish to send a hard copy response please post it, with a completed copy of the response form, to:

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1. About this consultation

This consultation seeks submissions from those interested or involved in all stages of the development and implementation of emerging biotechnologies. We especially welcome responses from those involved in the development of emerging biotechnologies, those with an interest in or concern about the use of specific emerging biotechnologies, and those involved in public engagement. The responses will inform the deliberations of a Nuffield Council on Bioethics Working Party on this topic.

In this consultation paper, we set out some background information and identify a number of broad issues and questions that arise in relation to emerging biotechnologies. Words underlined in the text are linked to, and explained in more detail in, the glossary.

Please feel free to answer as many or as few questions as you wish, and to take them in any order you wish. The questions are designed to be open-ended and when responding you should feel free to interpret questions in a way that fits best with your own experience or knowledge. We are particularly interested in learning from any concrete examples that you may provide. Please, also, feel free to highlight any issues connected with our Terms of Reference that are not covered in this paper.

The questions are not aimed specifically at either individuals or organisations, or at those with any one kind of expertise or knowledge rather than another. We are not aiming to gather quantitative data; therefore, please feel free to respond with your own personal views, with comments on a range of views of which you are aware, or with your organisation's policy on the issues raised, as appropriate.

2. Introduction and background

The Nuffield Council on Bioethics has established a Working Party to examine the social and ethical issues relating to 'emerging biotechnologies'. The objective of the Working Party is to develop principles and recommendations to assist decision makers to reach ethically informed judgements relating to emerging biotechnologies. These decision makers might include public policy makers, regulators, academic researchers, funding bodies and those involved in public engagement.

The term 'emerging biotechnologies' is open to interpretation but examples of what we mean by it include:

- genetically modified (GM) crops;
- human enhancement technologies;
- nanotechnology;
- regenerative medicine;
- synthetic biology; and
- xenotransplantation.

There are many more examples, springing from a wide range of different fields of research and innovation. We are interested in responses that reflect the full breadth and diversity of emerging biotechnologies. In particular, we are interested in the issues and themes that are common to the emergence of a broad range of biotechnologies and to the way in which society and policy makers respond to them.

Our focus will be on the social, ethical, legal and policy issues raised by emerging biotechnologies, including:

- benefits and harms (for example, improvements to health or damage to the environment) including those arising from misuse or deliberate threats;
- uncertainty and risk (for example, how we should act in situations where we have incomplete knowledge or what difficulties arise in incorporating unknown risks into decision making processes);
- precaution and innovation (for example, how a precautionary approach might threaten or guide innovation);
- ownership and control (for example, the design and effect of measures to protect intellectual property and constraints on these, such as ethical restrictions on patenting);

- markets and the economy (for example, how some technologies might 'disrupt' markets or how economic forces might shape technological development);
- the notion of 'progress' (for example, whether and how we might identify and measure progress as a result of technological development);
- social and cultural impacts (for example, how to identify and pursue the most desirable distribution of goods between individuals, groups or generations, and whether some technologies inherently widen the gap between the rich and the poor);
- international aspects (for example, whether some technologies might help or harm developing economies or otherwise affect relations between different peoples and societies); and
- technological diversity (for example, what benefits or dangers might arise as a result of technological standardisation and 'lock-in', or the existence of a plurality or technological pathways).

We expect to explore the way in which a range of different professionals and publics obtain and use information, form judgements, and understand risk, uncertainty and ambiguity. We also expect to investigate the implications of emerging biotechnologies for policy, governance and public engagement, and how various types of public engagement can inform responses to emerging biotechnologies.

3. Emerging technologies

To describe a technology as 'emerging' might simply be to imply that it is relatively new and not, as yet, accepted into routine use. However, the term 'emerging technology' has acquired a more complex meaning that, despite its increasingly widespread use, is difficult to define precisely.

'Emerging technologies' have been described as ones that:

- arise from new knowledge, or the innovative application of existing knowledge;
- lead to the rapid development of new capabilities;
- are projected to have significant systemic and long-lasting economic, social and political impacts;
- create new opportunities for and challenges to addressing global issues; and
- have the potential to disrupt or create entire industries.[1]

While this is only one possible description and different perspectives will draw attention to different features, it shows how most references to emerging technologies imply something more than merely the incremental development of a new invention, technique or process from proof of concept through testing and validation to acceptance into routine use.

Emerging *bio*technologies – the subject of our consultation – are those emerging technologies with a biological basis or use. Without settling on a definition of emerging biotechnologies for the time being we can nevertheless suggest certain features that may characterise them (although not necessarily all of them) and by which they might be recognised.

The developmental pathway followed by these technologies may vary considerably. Some emerging biotechnologies that were conceived decades ago have taken a long time or have not (yet) achieved their original promise (e.g. xenotransplantation) while others have been implemented relatively quickly (e.g. preimplantation genetic diagnosis); some are in early stages of use with uncertain prospects (e.g. genomic medicine) while others are at early stages of research (e.g. synthetic biology) with an uncertain range of uses.

Emerging biotechnologies may range from techniques (with, initially, a single, specific and limited use) to programmes (which encompass many techniques). Techniques may emerge by finding a variety of, often highly diverse, uses (such as polymerase chain reaction, which underpins genetic

[1] Harper T (2010) The long journey from nanotechnology to emerging technologies.

testing from healthcare to law enforcement and genealogy, or in vitro fertilisation, which underpins preimplantation genetic testing for diverse a range of purposes). Programmes, on the other hand, may draw on many different techniques (for example, human enhancement technologies, which draw on distinct innovations in pharmacology, surgery, computing, engineering, and cellular medicine among other things). This may present problems for ethical, policy, funding and regulatory frameworks, in that they may be applied to a technique in one of its many uses but not others, or to a programme but not to all of the techniques that underpin it.

Typically, there are significant uncertainties about the risks associated with an emerging biotechnology and considerable dispute about these. This may be due to its novelty, making it hard to draw inferences about risk by analogy to familiar technologies, or simply because the risks have not yet been well researched. This can lead to exaggerated claims both for and against the technology, and criticism of its proponents or opponents. Whether a technology is considered to be 'emerging' or not may be related to whether it is demonstrated to raise particular issues, whether it might raise such issues or whether (and by whom) it is claimed to raise those issues.

Often, emerging biotechnologies have the capacity to generate significant controversy (for example genetically modified crops or synthetic biology). This may be because of uncertainty or disagreement about the nature and level of associated risks. It also may be because they disturb familiar distinctions that are associated with established values, such as the distinction between the natural and the artificial (as when cloned animals are introduced into the food chain) or between human and non-human (as with the creation of human-animal 'admixed' embryos). Controversies can be particularly heightened where there is a possibility that the technology could be used for anti-social or criminal purposes.

Emerging biotechnologies may present important decisions for policy makers because they entail a commitment of resources or foreclose the development of an alternative approach. Alternatively, bans or over-restrictive regulation can lead to the delay or loss of valuable benefits. In some cases, the significance of a policy decision, or even that the opportunity for making a decision was present at all, may only be recognised after the fact, by which time it may have become difficult to reverse.

Emerging biotechnologies often have an interdisciplinary character, drawing on knowledge originating in a variety of more established fields. Novelty (of approach and perspective), convergence (between fields and practices), and divergence (from an established 'parent' field) may be characteristic features. Emerging technologies tend to be associated with the development of new

concepts and give rise to new kinds of problem or 'unlock' new perspectives. They tend to be fertile sources of novel technical terms (for example, the concept of a 'biobrick' in synthetic biology).

Our initial aim will be to identify key features of emerging biotechnologies and the implications of these for the way we approach them from the point of view of ethics and public policy.

Questions

1	How would you define an 'emerging technology' and an 'emerging biotechnology'? How have these terms been used by others?
2	Do you think that there are there features that are essential or common to emerging biotechnologies? (If so, please indicate what you think these are.)
3	What currently emerging biotechnologies do you consider have the most important implications ethically, socially and legally?

4. Cultural, international and historical context

A variety of contextual factors can influence the development and introduction of biotechnologies, as well as their reception by professionals, policy makers and publics. These may include social, cultural, economic and political factors.

Some groups or societies adopt certain technologies more readily than others. This might be for a number of different reasons, ranging from those intrinsic to the identity of the group (such as a commitment to individual autonomy or to a particular religious faith) to those that are merely contingent (such as ownership of the technology or reaction to the displacement of traditional industries). An example of differing societal responses to the same technology can be found in the European and North American reactions to genetically modified (GM) crops: public opposition to GM crops in Europe had decisive consequences, whereas there was comparatively little such opposition in North America.

Different research pathways may be followed in different countries as a consequence of prevailing cultural attitudes and standards of behaviour, and the extent to which markets, public funding and governance frameworks reflect these attitudes and standards. For example, human embryonic stem cell research has been conducted both publicly and privately in the UK, while in the USA federal funding in that area was specifically restricted for a long period.

While the European reaction to GM crops has, for the most part, been negative, European public reaction to other genetic technologies, for example in human therapeutic agents (such as the artificial production of human insulin) has been comparatively muted. The public reaction to GM crops in Europe was not foreseen or, at least, was not provided for in advance by those developing the technology. This experience has led to significant re-thinking of how new technologies are introduced and presented to the public (see Section 5).

Companies and markets are increasingly globalised. For example, a substantial amount of research and development activity for companies that have their head offices and financial base in Europe and the US now takes place in China, India and South East Asia. Until recently, the market forces, cultural attitudes and standards of behaviour of 'Western' nations have been the dominant forces driving the development and implementation of much advanced technology. The increasing cultural, economic and political influence of non-Western countries and cultures on research promises to

have consequences for the pathways followed in technological development. This may come about through the prioritisation of goals (for example, public health measures as opposed to advanced therapies), the allocation of values or the definition of progress more generally. On the other hand, the globalisation of markets, and the increasingly multinational character of organisations and institutions may transform cultural distinctions or diminish their relevance.

Finally, the nature of political systems themselves, and the geopolitical context, may also influence the rate and manner of development of technologies (for example, rocket technologies during the 'space race' between the USA and USSR, or the development of cybernetics during the second world war).

In the course of our deliberations, we expect to consider the nature and importance of social, cultural and geopolitical influences on the acceptability of particular types of research and technology innovation, and on professional, policy and public responses to them.

Questions

4	Are there examples where social, cultural and geographical factors have influenced the development of emerging biotechnologies (either in the past or currently)?
5	Are there examples where social, cultural and geographical factors have influenced public acceptance or rejection of emerging biotechnologies?
6	Are there examples where internationalisation or globalisation of research, markets and regulation have influenced the development of emerging biotechnologies?
7	How have political traditions (such as liberal democracy) and political conditions (e.g. war) influenced the emergence of biotechnologies?

5. Ethical, policy and public engagement issues

The emergence of new biotechnologies gives rise to questions about whether, in what conditions, and subject to what controls they should be put to use, in other words, questions of ethics and public policy. Public engagement is one way in which the developers of technology and policy makers can involve, accommodate and influence views about what *should* be done in a particular social and historical setting, rather than simply what *can* be done in a laboratory or experimental setting.

Ethical issues

Ethics is a branch of philosophy that concerns what we ought or ought not to do; it involves the study of values and moral reasoning, and their application to human conduct. Bioethics is a branch of applied ethics that deals with moral problems arising from the life sciences.

We want to identify and explore the ethical values and interests that are relevant to emerging biotechnologies. We want to understand whether there are ethical principles that may have relevance specifically to emerging biotechnologies and how these principles might be applied, and to find the proper role of moral reasoning in relation to emerging biotechnologies.

Below, we describe a number of ethical issues that we think may be relevant to emerging biotechnologies. We do not wish to suggest that this is an exhaustive list and we invite respondents to reject, elaborate or add to these in their responses.

Human intervention in nature

Concerns have been raised about the capacity of certain biotechnologies, such as genetic engineering and synthetic biology, to change the relationship between human beings and the natural world in morally undesirable ways. There are concerns that these biotechnologies inappropriately elevate human agency (so-called 'playing God'), instrumentalise other living beings, create a capacity for intervention in the natural world that is undesirable in itself, and disrupt distinctions to which people attach moral significance (such as that between humans and non-humans).

Harms to health

Ethical issues arise when the use of technologies is believed, by at least some, to be potentially harmful to the health of individuals or populations, or to have a capacity for harm as well as benefit. It has been suggested that

nanotechnology, for example, has this capacity. It is important to consider the significance of such beliefs and the respect that is due to them, as well as what can be known about the balance between potential harm and potential benefits arising from the technologies in question, and how these depend on context and perspective.

Environmental harm

In addition to potentially detrimental effects on human wellbeing, the effect a certain technology (e.g. genetically modified (GM) crops) might have on the environment, natural ecologies and other living things (for example, habitat destruction or pollution) may also give rise to significant ethical concerns.

Human nature

Technologies that are perceived to challenge common understanding of what it is to be human often give rise to controversy. For example, xenotransplantation or human enhancement technologies that might, in the future, significantly alter human cognitive or physical capacities, might eventually call into question how we identify a given person as human. Developments like these can challenge value systems that attach to concepts such as human integrity, human nature and human dignity.

Social and intergenerational justice

There are concerns that some emerging biotechnologies may widen the gap between the rich and the poor, at both a national level (e.g. the emergence of a genetic underclass of people who are excluded from certain forms of social participation because of their genetic inheritance) and an international level (e.g. developing economies being excluded from benefit sharing or lacking a knowledge base, facilities and/or funding for licensed products or components).

Some emerging biotechnologies, such as GM crops or synthetic biology, have global implications: they are likely to involve multinational companies and the transfer of money, products and people between countries. However, this may become unavoidable if, for example, advanced agricultural biotechnologies hold the only feasible long-term approach to maintaining an adequate food supply in some parts of the world.

The consequences of implementing (or not implementing) new technologies may have an impact on future generations (e.g. spent nuclear fuel storage). Where this is the case we need to consider the obligations that the present generation owes to those that follow it and the risks and benefits of new developments for future generations.

Policy issues

In simple terms, a policy can be defined as a decision, or set of decisions to guide action (or deliberate inaction), adopted by an organisation or government. For the purposes of this consultation, we are primarily concerned with the policies of those with a significant interest in or influence over the development and implementation of one or more emerging biotechnologies. This includes government departments, funding bodies, private firms, professional bodies and interest groups.

Policy issues are important to consider in this context because they relate to how ethical issues are addressed in practice: ethical judgements identify what *ought* to be done; policy decisions address how those judgements are given effect in a complex context of motives and interests. We outline some of these issues that we think are relevant to emerging biotechnologies below.

Research and innovation

New technologies are often seen as an important way of driving economic and social development. Governments and societies therefore have an interest in, for example, investing in or stimulating research, and maintaining systems for the protection of intellectual property (IP). Policy makers commonly strive to encourage investment without stifling research or restricting benefits. For example, excessively broad claims in granted patents might inhibit the incentive for third party research in the area 'staked out' by such claims, whilst a lack of IP protection may remove commercial incentives to commit resources to research and development of technologies for which there is a pressing social need. The open source movement is likely to have an increasing influence in some areas of technological development, such as software engineering and synthetic biology

Intellectual property systems may themselves include ethically-based constraints on the grant of patents (for example, the European Patent Office does not allow the patenting of products the production of which necessarily involves the destruction of human embryos), or may have difficulty incorporating *entirely* novel techniques and artefacts.

Funding and investment policies will need to consider the risks of investing in one, or a limited number of, technologies that have yet to establish their potential. There are risks to a technology becoming 'locked in' simply because of vested commercial (or other) interests, effectively stifling the development of other technologies with, potentially, a different range of benefits. Examples of 'lock-in' include the widespread adoption of the VHS (rather than the competing Betamax) standard of consumer video tapes

during the late 1970s and early 1980s, or the widespread adoption of QWERTY-layout keyboards. It should be emphasised, however, that technological lock-in and standardisation can also generate benefits, such as substantial efficiency gains.

Responses to risk and uncertainty

Health and safety concerns can be identified by carrying out risk assessments, which, in turn, support the development of risk management strategies. However, the effectiveness of risk assessment is limited by the possible existence of unknown or unpredictable effects and by contending interests and values and it is questionable how much this can be overcome simply by more work to evaluate long-term social and environmental risks relating to emerging biotechnologies.

One regulatory response to unknown risk is to adopt the 'precautionary principle'. This involves recognition that *absence of evidence of harm* is not necessarily *evidence of absence of harm* and that regulation should take account of unquantifiable uncertainties, for instance, by acting cautiously in the face of any potential for serious or irreversible harm. A conservative interpretation of this principle might require that evidence of the absence of all risk should be demonstrated before research in a new area is carried out or the release of substances into the environment goes ahead. At the other extreme, some advocate a 'proactionary principle' in certain contexts, whereby new developments should be considered safe unless and until proven otherwise. All positions on this spectrum may involve ethical commitments and proceed from virtuous intentions, but they can have significantly different consequences for the degree and direction of progress in new technologies, and the potential for delivering anticipated benefits.

The Nuffield Council on Bioethics' report, *The use of genetically modified crops in developing countries*,[2] recommended that the risks inherent in an existing situation should not be overlooked in any assessment of whether to introduce a new development. The paper concluded that an adequate interpretation of the precautionary approach would require comparison of the risks of the status quo with those posed by possible paths of action. However, any comparison remains limited by the presence of unquantifiable uncertainty and in any given case the risks may be offset by positive benefits.

The design of regulatory systems

[2] Nuffield Council on Bioethics (2004) *The use of genetically modified crops in developing countries: a follow-up discussion paper*.

Regulatory systems provide a way of managing harm, risk, uncertainty and ambiguity whilst helping to steer the direction of technological developments in order to deliver those outcomes considered most desirable. Regulation can be used to guard against specific, known harms (e.g. health and safety inspection of restaurants), to identify potential new harms (e.g. testing of new pharmaceutical products), to secure specific benefits or distribution of benefit (e.g. drug pricing) or to protect against moral hazard (e.g. licensing of human embryo research). Regulation can also have the effect of stabilising certain technology trajectories rather than others and of protecting vested interests.

If it is the case that emerging biotechnologies give rise to potential harms (whether physical or moral), uncertainty with regard to future risk and benefit and various ethical concerns, then a regulatory response may be appropriate. Existing regulatory measures may be capable of adequately handling some, but not all, types of emerging biotechnology. However, a single regulatory mechanism may not be well adapted to all new biotechnologies, owing to their diverse nature and the different types and levels of risk associated with each. A question that we will need to address, therefore, is whether it is possible or desirable to develop a coherent approach to regulation or a set of regulatory options that could support policy objectives such as to encourage and stimulate innovation, avoid the risk of 'locking in' a single or limited set of technologies, maintain proportionate mechanisms for protecting against undue risk of harm and secure an appropriate distribution of benefits. Moreover, even if a single regulatory design were appropriate, this still leaves open many questions that face regulatory systems generally: for instance, finding the appropriate balance between self-regulation and legal prescription in the system. Alongside these issues there is a need to consider the important role played by regulation, not just in reducing 'risk' or 'harm', but also in helping to steer whatever are held to be the most desirable directions for technological development.

Public engagement

Public engagement may take many forms, for example: inquiries, written consultation exercises, seminars, focus groups, surveys, deliberative polls, citizens' juries, consensus and dissensus conferences, mapping and scenario exercises, and stakeholder commissions.

The early development and adoption of many of these practices lay in the desire of some research scientists, mostly in universities, to respond to what they perceived to be growing levels of public detachment and mistrust towards the sciences in general, as the sciences became increasingly

specialised and remote from everyday experience. Thus, they set about informing the public about their work to improve 'scientific literacy', often with the underlying assumption that 'improved' understanding would lead to greater acceptance. Since then, moves have been made towards less asymmetrical, more dialogue-focused models that recognise the significance of the contribution of non-scientists to debates about science and technology policy. There is now increasing interest in moving public engagement 'upstream', to a point before significant research or development have been undertaken and before the representation of a technology to non-specialists has become established or social attitudes towards it have become defined.

All forms of public engagement have in common their potential, not only to foster understanding, trust and acceptance for particular types of technology development, but also to inform wider policy debates and decisions with possible alternative trajectories and their associated advantages, disadvantages and uncertainties. The role of public engagement can be, therefore, as much to open up alternative technological possibilities, as to compound existing processes through which these may be closed down. In this way, public engagement can be supportive and complementary to existing procedures for democratic decision making and accountability.

The significance of public engagement for emerging biotechnologies

The opinions and values of different publics may be important considerations in relation to the development and implementation of technology, especially if the technologies in question have potentially significant societal impacts or if public money is funding research. Public engagement in relation to emerging technologies itself merits consideration given that a number of emerging technologies (for example, synthetic biology and nanotechnology) have been the subject of recent public engagement activities and that public engagement activities have themselves been the subject of some controversy.

Issues that arise in relation to public opinion and public engagement

The interests, values, knowledge, reasoning and conclusions of those who comprise the public or publics in relation to a particular emerging technology can be diverse, complex and dynamic. In view of this, it is unsurprising that methods of quantifying the opinions of various groups within the general public, especially in relation to complex technologies where information must be provided before questions can be asked meaningfully, are open to criticisms of bias and manipulation. Smaller scale, qualitative approaches, on the other hand, are open to the accusation that they are un-representative of the views and preferences of the public as a whole. Public engagement, seen

more broadly, therefore goes beyond narrow notions of public opinion, to address wider social aspects, cultural values and political interests. Understanding these and their significance for practical decisions presents considerable challenges. These include creating a space in which genuine engagement can take place, understanding how different individuals or groups access information, exchanging appropriate information in a meaningful way, understanding how opinions can change and be manipulated, and resolving differing views on the proper modes, place and role for public engagement.

The understanding and evaluation of risk may also differ between experts and the public, and is open to influence from a number of factors, such as the media, professional status and economic interest. Health specialists often find it much more difficult to cultivate media interest in proven health risks, such as smoking, alcohol and obesity, than in, for example, 'crises' such as the severe acute respiratory syndrome (SARS) virus, which pose relatively little danger to the population as a whole. Limited public understanding of statistics is often considered to be a problem by experts; on the other hand, there may be a tendency for some experts to focus on quantifiable risk, as opposed to less determinate uncertainties, ambiguities and the prospect of surprise.

The attempted introduction of GM crops into Europe, particularly the UK, again usefully illustrates many of these issues. It was widely criticised (for different reasons) by both those for and against their introduction for, (depending on the perspective) poor or biased presentation of the perceived risks or a failure to understand the risks as presented, and for being an attempt to incorporate democratic decision making into ethically problematic areas or a token, cynical strategy to disarm dissenting groups.

Despite this, or perhaps in response to the issues raised by that experience and others like it, there has been a considerable growth and sophistication of public engagement activity, especially in relation to emerging technologies (such as synthetic biology, nanotechnology and stem cell research). Public engagement has been identified as an early priority, for example, for those involved with the development of synthetic biology and there is evidence that lessons are being learned from past experiences; indeed, effective public engagement has been identified as a factor critical to the development of synthetic biology.

Questions

General

8 Are there ethical or policy issues that are common to most or many emerging biotechnologies? Are there ethical or policy issues that are specific to emerging biotechnologies? Which of these, if any, are the most important?

9 Do you think that some social and ethical themes are commonly overlooked in discussions about emerging biotechnologies? If so, what are they?

10 What evidence is there that ethical, social and policy issues have affected decisions in (i) setting research priorities, (ii) setting priorities for technological development, and (iii) deploying emerging biotechnologies, in either the public or private sector?

Ethics

11 What ethical principles should be taken into account when considering emerging biotechnologies? Are any of these specific to emerging biotechnologies? Which are the most important?

12 Who should bear responsibility for decision making at each stage of the development of an emerging biotechnology? Is there a clear chain of accountability if a risk of adverse effects is realised?

Policy

13 What roles have 'risk' and 'precaution' played in policy decisions concerning emerging biotechnologies?

14 To what extent is it possible or desirable to regulate emerging biotechnologies via a single framework as opposed to individually or in small clusters?

Public engagement

15 What role should public opinion play in the development of policy around emerging biotechnologies?

16 What public engagement activities are, or are not, particularly valuable with respect to emerging biotechnologies? How should we evaluate public engagement activities?

17	Is there something unique about emerging biotechnologies, relative to other complex areas of government policy making, that requires special kinds of public engagement outside the normal democratic channels?

List of questions

Please illustrate your responses, wherever possible, with specific examples. These may be drawn from your own experience or from other sources of which you are aware. Where you refer to other sources of information, it would be helpful to us if you would indicate the source.

1	How would you define an 'emerging technology' and an 'emerging biotechnology'? How have these terms been used by others?
2	Do you think that there are there features that are essential or common to emerging biotechnologies? (If so, please indicate what you think these are.)
3	What currently emerging biotechnologies do you consider have the most important implications ethically, socially and legally?
4	Are there examples where social, cultural and geographical factors have influenced the development of emerging biotechnologies (either in the past or currently)?
5	Are there examples where social, cultural and geographical factors have influenced public acceptance or rejection of emerging biotechnologies?
6	Are there examples where internationalisation or globalisation of research, markets and regulation have influenced the development of emerging biotechnologies?
7	How have political traditions (such as liberal democracy) and political conditions (e.g. war) influenced the emergence of biotechnologies?
8	Are there ethical or policy issues that are common to most or many emerging biotechnologies? Are there ethical or policy issues that are specific to emerging biotechnologies? Which of these, if any, are the most important?
9	Do you think that some social and ethical themes are commonly overlooked in discussions about emerging biotechnologies? If so, what are they?
10	What evidence is there that ethical, social and policy issues have affected decisions in (i) setting research priorities, (ii) setting priorities for technological development, and (iii) deploying emerging biotechnologies, in either the public or private sector?

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Glossary

Applied ethics: the application of moral reasoning to concrete problems concerning the value of one course of action as opposed to another.

Biotechnology: the use of biological processes to manufacture products.

Citizens' juries: a type of public engagement whereby a group of non-specialists takes evidence relevant to a particular policy question from a variety of sources and then uses this evidence in deliberation leading to a 'verdict' or set of conclusions.

Cybernetics: an interdisciplinary field of study related to control and communications in complex electronic systems and in animals.

Ethics: a branch of philosophy concerned with the study of values and moral reasoning, and their application to human conduct.

Genetic engineering: the technology used to genetically manipulate living cells to produce new chemicals or perform new functions.

Genetic modification: a technology that allows selected individual genes to be transferred from one organism into another, including genes from unrelated species. The technology can be used, for example, to promote a desirable crop characteristic or to suppress an undesirable trait.

Genomic medicine: the use of genomic information and technologies to determine disease risk and predisposition, diagnosis and prognosis, and the selection and prioritisation of therapeutic options; it is concerned with the properties and interactions of the DNA in an organism rather than the inheritance of particular genes or genetic mutations.

Human enhancement technologies: technologies that aim to artificially overcome human physical or mental limitations. The term includes a number of potential approaches including computational, genetic, neurological, pharmaceutical and robotic technologies. Enhancement is often contrasted with therapy, which is generally seen to be the restoration of a particular physical or mental condition or set of conditions.

Human therapeutic agents: a substance that causes therapeutic effect in humans, i.e. one that restores a physical or mental condition or set of conditions to a desirable state.

In vitro fertilisation: fertilisation 'in glass' (i.e. in the laboratory), as opposed to in the body (in vivo). Eggs are removed from the body (often following artificial stimulation of the ovaries) and mixed or injected with sperm. A resulting embryo may then be transferred to a woman's uterus with the intention of establishing a pregnancy.

Intellectual property: an intangible form of personal property. Patents, copyrights, trademarks, service marks, trade names and trade secrets are examples of intellectual property.

Moral hazard: the tendency of an individual or group, when insulated from the consequences of their actions, to act in a way that is more likely to bring about those consequences (for example, when insured people act in a way more likely to bring about the state of affairs against which they are insured).

Nanotechnology: basic and applied science concerning materials at a scale of up to 100 nanometres. A nanometre is one billionth of a metre (1×10^{-9} metres).

Nuffield Council on Bioethics: an independent body that examines and reports on ethical issues in biology and medicine. It was established by the Trustees of the Nuffield Foundation in 1991, and since 1994 it has been funded jointly by the Foundation, the Wellcome Trust and the Medical Research Council.

Open source: an approach to design, development, production and distribution that seeks to encourage and enable public access to the fundamental resources upon which a product is based or constructed. Commonly applied to software engineering where the source code would be published freely, the term it is now applied to many fields including, for example, synthetic biology.

Polymerase chain reaction: a technique used in genetic testing that involves copying the complementary strands of a target DNA molecule simultaneously for a series of cycles until the desired amount is obtained.

Precautionary principle/precautionary approach: a rule or approach that recommends restrictions on activities if there is a perceived risk of damage to the environment or to human health. Its interpretation is disputed.

Preimplantation genetic testing/diagnosis: a technique used to determine whether an embryo created by in vitro fertilisation carries a genetic disease or trait, prior to it being transferred to the uterus.

Proactionary principle: the principle that new developments should be considered safe unless and until proven otherwise.

Regenerative medicine: interventions that aim to provide for the repair of organs, tissue or cells. Often uses stem cells to replace damaged or diseased tissues.

Research and development: work directed towards the innovation, introduction and improvement of products and processes. The term is used primarily in the private sector.

Stem cells: undifferentiated cells, which can divide indefinitely and produce either more stem cells or cells that commit to becoming more specialised (differentiated) cell types. Can be used in regenerative medicine to repair damaged or diseased tissues or organs.

Synthetic biology: the use of principles derived from biology, chemistry and engineering for the construction of novel biological networks/organisms with bespoke properties (or the re-construction of pre-existing organisms for specific purposes), using standardised biological parts that are well-characterised and have known functions.

Working Party: a group of experts appointed by the Nuffield Council on Bioethics to examine and report on a topic identified by the Council. Members of a Working Party are chosen to represent a wide range of experience and skills.

Xenotransplantation: the transplantation of organs, tissue or cells from one species to another.

Working Party Terms of Reference

1. To examine common social, ethical and legal issues raised by emerging biotechnologies, in particular the implications for policy, governance and public engagement.
2. To explore issues of benefits, harms, risk, precaution, uncertainty, public perception and intellectual property related to emerging biotechnologies.
3. To consider the above areas in light of the historical and social context in which biotechnologies have in the past developed and been received and managed.
4. To draft a report and make recommendations on research, policy, governance and public engagement.