

Appendices

Appendix 1: Method of working

Background

The Nuffield Council on Bioethics established the Working Party on 'Emerging biotechnologies' in January 2011. The Working Party met eleven times over a period of 18 months. In order to inform its deliberations, it held an open consultation and a series of 'fact-finding' meetings with external stakeholders and invited experts. It also commissioned two reports on topics relevant to the work of the project and received comments on a draft of the Report from 12 external reviewers. Further details of each of these aspects of the Working Party's work are given below and in Appendix 2. The Working Party would like to express its gratitude to all those involved for the invaluable contribution they made to the development of the final Report.

Consultation document

The Working Party launched a consultation in April 2011, which ran until July 2011. 84 responses were received, of which 48 were submitted by individuals and 36 on behalf of organisations. Those responding to the consultation included students, academics, faith groups and professional organisations. A full list of those responding is set out in Appendix 2. A summary of the responses is available on the Council's website. Copies of individual responses will also be made available on the website in those instances where the Council has permission from respondents to do so.

Fact-finding

As part of its work, the Working Party held a series of 'fact-finding' meetings, the details of which can be found below. (Details reflect affiliations at the time of the meetings.)

Research and development: 6 May 2011

- **Dr Jim Ajioka**, Department of Pathology, Parasitology Group, University of Cambridge
- **Professor Robert Brown**, Head of Tissue Repair and Engineering Centre, University College London
- **Professor Keith Campbell**, Professor of Animal Science, Nottingham University
- **Professor Olivier Danos**, Cancer Institute, Gene Therapy Group, University College London
- **Mr Alexander L Green**, Spalding Senior Lecturer and Consultant Neurosurgeon, John Radcliffe Hospital, Oxford
- **Professor Richard Kitney OBE**, Professor of Biomedical Systems Engineering, Imperial College London
- **Professor Dek Woolfson**, School of Biochemistry, University of Bristol

The role of public engagement: 6 May 2011

- **Professor Martin Bauer**, Head of the Methodology Institute and Professor of Social Psychology and Research Methodology, London School of Economics and Political Science
- **Mr Simon Burall**, Director, Involve
- **Dr Jason Chilvers**, Lecturer in Environmental Management, University of East Anglia
- **Dr Clare Matterson**, Director, Medical Humanities and Engagement, Wellcome Trust
- **Dr Patrick Middleton**, Head of Public Engagement, BBSRC
- **Dr Alison Park**, Head of Society and Social Change, National Centre for Social Research
- **Dr Tom Wells**, Department for Business, Innovation and Skills

Intellectual property, innovation and markets: 24 June 2011

- **Dr Graham Bell**, TSB
- **Dr Nicki Curtis**, Senior Policy Advisor, IPO
- **Dr Tim Harper**, Director, Cientifica
- **Professor Douglas Kell**, Chief Executive, BBSRC

- **Dr Denis Koltsov**, Information Manager, the Nanotechnology Industries Association
- **Dr Steve Musgrave**, Founding Partner, Unicorn Biologics
- **Ms Vicki Salmon**, Partner, IP Asset
- **Dr Nigel Sansom**, Senior Manager for Technology Introduction, NHS Innovation
- **Dr Richard Seabrook**, Business Development Manager, Wellcome Trust

Policy, regulation and governance: 8 July 2011

- **Dr Mark Bale**, Interim Director, Health Science & Bioethics Division, Department of Health
- **Dr Tim Brooks**, National Specialist, Centre for Emergency Preparedness and Response, Rare and Imported Pathogens Laboratory, HPA
- **Professor Jim Dunwell**, Member of ACRE
- **Dr Neil Ebenezer**, Head of New and Emerging Technologies, Devices Division, MHRA
- **Dr Katherine MacGregor**, Policy Advisor, Royal Academy of Engineering
- **Professor Robin Lovell-Badge**, Academy of Medical Sciences
- **Dr Catherine Rhodes**, Institute for Science, Ethics and Innovation, University of Manchester
- **Dr Jack Stilgoe**, Senior Research Fellow, University of Exeter
- **Ms Hilary Sutcliffe**, Director, MATTER
- **Professor David Wield**, Director, ESRC Innogen

Evidence reviews

In order to inform its deliberations, the Working Party commissioned two additional reports. These covered: the sources and allocation of funding for research and development of biotechnologies; and, the analytical significance of the concept and property of ‘emergence’ in the patent system.

The terms of each review are set out below.

Review 1: Emerging biotechnologies: can we find out who funds R&D and what they support?

Purpose: to assist the Working Party in understanding:

1. existing patterns of national and international research funding (or resource allocation) in the field of biotechnology; and
2. the extent to which these data can be reasonably acquired and the limitations of the relevant methodologies.

The review was carried out by Dr Michael Hopkins of SPRU (Science and Technology Policy Research), University of Sussex. The review did not seek to provide a comprehensive analysis of existing sources providing data on biomedical funding but, rather, presented illustrations of the forms in which data are available.

Review 2: The analytical significance of emergence in the patent system

Purpose:

1. to assist the Working Party in understanding the intellectual property system as it applies to emerging biotechnologies and, in particular:
 - challenges for the IP system posed by emerging biotechnologies and how the IP system has responded/might respond to these; and
 - challenges posed by the IP system for emerging biotechnologies and how the practitioners have responded/might respond to these

2. To provide data and concrete examples to support this analysis
3. To assist the Working Party to draw conclusions about how decisions about IP conditions that influence (limit, facilitate, control, direct, etc.) the emergence of biotechnologies should be framed and advice that should be taken into consideration.

The review was carried out by Dr Siva Thambisetty, London School of Economics and Political Science and was informed by work on an EPSRC Discipline Hopping Award on synthetic biology. The review was largely based on secondary research.

External review

An earlier version of this Report was reviewed by 12 individuals with expertise in disciplines relevant to different aspects the project. These individuals were:

- Dr Tavis Bayer
- Professor Julia Black
- Professor Martin Bobrow
- Professor John Dupré
- Dr Yasemin J Erden
- Dr Shawn Harmon
- Professor Stephen Hughes
- Professor Sheila Jasanoff
- Dr Paul Nightingale
- Professor Judith Petts
- Professor Dietram A Scheufele
- Professor Philip Scranton

The Working Party deeply appreciates the time and thought the reviewers brought to this task and thanks them for their helpful contributions.

The views expressed within this Report are those of the Working Party and the Council and do not necessarily reflect the views of any participants in the various activities undertaken by the Working Party in connection with this Report.

Appendix 2: Wider consultation for the Report

The aim of the consultation was to obtain views from as wide a range of organisations and individuals interested in the area as possible. The consultation document was published online and made available in hard copy on request. Individuals and organisations that the Working Party expected to have a particular interest were also directly alerted by email and encouraged to respond. The document was divided into three main substantive parts:

- the nature and identity of emerging technologies;
- the cultural, international and historical context; and
- the relevant ethical, policy and public engagement issues.

In total, 17 questions were posed, and respondents were encouraged to answer as many, or as few, as they wished. Eighty four responses were received, 48 from individuals and 36 from organisations. Eight respondents wished to remain anonymous. All the responses were circulated to Working Party members and a summary of responses was considered in detail at a subsequent Working Party meeting.

A summary of the responses received, together with the original consultation paper, is available on the Council's website.⁷⁰⁶ Individual responses will also be published in full on the website, where respondents have given permission for the Council to do so. The responses received played an important role in shaping the Working Party's thinking, and the Working Party is grateful to all those who contributed.

Anonymous

Eight respondents wished to remain unlisted.

Individuals

- Professor Jayapaul Azariah, Founder President, All India Bioethics Association
- S. Bonny
- Professor Derek Burke
- Professor Raphael Cohen-Almagor, University of Hull
- Mr K.R Coleman
- Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague
- Dr Sara Fovargue, Law School, Lancaster University
- Dr Caroline E Foster
- Dr Christopher French
- Professor Robert T Hall, Profesor de Bioética, Facultad de Química, Universidad Autónoma de Querétaro, Mexico
- Dr Olivia Harvey
- Jonathan Harwood
- Elisabeth Hildt, University of Mainz
- Yutaka Hishiyama

⁷⁰⁶ See: <http://www.nuffieldbioethics.org/emerging-biotechnologies/emerging-biotechnologies-consultation>.

- David S Jones, Massachusetts Institute of Technology
- Masaru Katoh
- Drew L Kershen, Professor of Law (USA)
- Leicester Medical School – Jake Smith, Ruth Jones, Ashish Patel, Aaron Dean, Catherine Heighton, Safiyah Surtee, Charu Thanvi, Callum Johnson, Joe Mortimer
- Leicester Medical School – Josh Brewin, Philip Cheng, Atyeh Hamedani, Odin Leung, Manisha Munyal, Francis Okoroh, Preeya Ummur, Anna Weatherill and Abigail Western.
- Leicester Medical School – Group 21
- Leicester Medical School – Louise Newton, Suzanne Holmes, Nicholas Green, Sasha Denny-Morley, Kassir Mahmood, Jognesh Mistry, Imran Ahmed
- Leicester Medical School – Rebecca Pierce, Rosie Allen, Edward Rogers, Krupa Samani, Amy Forsyth, Heather Buckby, Rae Clark, Abdul Hassan
- Leicester Medical School – David Ademidun, Wayne Mitchell, Jennifer Kwan, Chloe Thomson, Jonaid Farid, Cara Booth, Francesca Lorford, Susannah Gurung, and Andrew Mabey
- Stefania Lymperi, PhD and Takis Vidalis, PhD, Senior Scientist, Hellenic National Bioethics Commission
- Luc Michel, Surgical Services, Catholic University of Louvain at Mont-Godinne Hospital
- Professor Vivian Moses
- Thomas E Nickson, PhD, Monsanto Company, St Louis, MO USA
- Inès Violeta Ortega Garcia
- Simone Penasa
- Professor Maude Phipps, Jeffrey Cheah School of Medicine & Health Sciences, Monash University
- Powell, Buchanan, Douglas & Savulescu
- Megan Quinlan, representing the MosqGuide Project, Imperial College London
- Mertxe de Renobales Scheifler, University of the Basque Country/EHU, Spain
- Sal Restivo & Sabrina Weiss, Renssalaer Polytechnic Institute
- Professor Bonnie Steinbock
- Hilary Sutcliffe - MATTER
- Professor Kevin Warwick
- Professor Sir David Weatherall
- Dr Alan R Williamson
- Go Yoshizawa, University of Tokyo

Organisations

- Agricultural Biotechnology Council (ABC)
- Bio Ethics Group, The Church in Wales
- British Embassy, Washington DC
- British High Commission Singapore
- British Medical Association
- British Science Association
- Centre for Bioethics & Emerging Technologies, St Mary's University College London
- Cesagen (ESRC Centre for Economic and Social Aspects of Genomics)
- Christian Medical Fellowship
- Egenis, University of Exeter
- ESRC Innogen Centre
- Federal Ethics Committee on Non-Human Biotechnology
- GeneWatch UK

- Government Office of Science, Department for Business, Innovation & Skills, Science and Innovation Network - Finland
- HEAL UoS (Health, Ethics and Law, University of Southampton) and CELS (Clinical Ethics and Law at Southampton)
- HeLEX Centre for Health, Law and Emerging Technologies; University of Oxford
- Humanist Society of Scotland
- John Innes Centre
- Medical Ethics Alliance
- Nishat Hyder, on behalf of ISEI and CSEP, University of Manchester
- Nowgen
- PHG Foundation
- Professor Nick Pidgeon, Cardiff University
- RCOphth (NB submission from Prof Dua, president of RCOphth)
- Research Councils UK
- Reverend Dr McCarthy, National Adviser, Medical Ethics and Health and Social Care Policy, The Archbishop's Council, the Church of England
- The Royal Academy of Engineering
- RSPCA
- Science and Innovation Network - India
- Science, Culture and the Law (SCuLE), University of Exeter School of Law
- Sense about Science
- UK Science and Innovation Network - Canada
- UK Science and Innovation Network - Switzerland (response compiled by Gaby Bloem)
- Antonio G. Spagnolo, Institute of Bioethics, School of Medicine "A. Gemelli", Università Cattolica del Sacro Cuore - Roma
- Value Addition to Genomic and GE3LS (VALGEN)
- Wellcome Trust

Appendix 3: The Working Party

Professor Michael Moran (Chair)

Michael Moran is Professor Emeritus of Government at the University of Manchester. His main interests lie in regulation, especially economic regulation. His publications include *Governing the Health Care State* (1999), *The British regulatory state* (2007) and *After the Great Complacency: financial crisis and the politics of reform* (2011).

Dr Jane Calvert

Jane Calvert is Reader in Science, Technology and Innovation Studies at the ESRC Innogen Centre. Her broad area of research is the sociology of the life sciences. She is currently studying the emergence and development of systems biology and synthetic biology. She is particularly interested in the role of social scientists in new scientific fields, the differences between biology and engineering, intellectual property and open source, and design and aesthetics in synthetic biology.

Mr Trevor Cook

Trevor Cook is a partner in the international law firm Bird & Bird LLP. He specialises in patent and other intellectual property litigation and advice and life sciences administrative law. In addition to numerous articles and several co-authored publications, he has written the following books – *A User's Guide to Patents* (2011), *EU intellectual property law* (2010), *Pharmaceuticals, biotechnology and the law* (2009), *A European perspective as to the extent to which experimental use, and certain other, defences to patent infringement, apply to differing types of research* (2006) and *The protection of regulatory data in the pharmaceutical and other sectors* (2000).

Professor David Edgerton

David Edgerton is Hans Rausing Professor at Imperial College London. He is the Founding Director of its Centre for the History of Science, Technology and Medicine. His most recent books are *The shock of the old: technology and global history since 1900* (Profile 2007) and *Britain's war machine: weapons resources and experts in the Second World War* (Allen Lane/Penguin, 2011).

Professor Ray Hill

Ray Hill was Head of Licensing and External Research for Europe at Merck, Sharp and Dohme until his retirement in May 2008. He is a pharmacologist with a special interest in pain and headache research and is a Visiting Professor at Imperial College London and Bristol, Surrey and Strathclyde Universities. He is a non-executive Director of several biotech companies and Honorary Biomedical Business Development Advisor at Imperial College London. He is President Emeritus of the British Pharmacological Society.

Professor Søren Holm

Søren Holm is Professor of Bioethics at the University of Manchester and part-time Professor of Medical Ethics at the University of Oslo, Norway. He is a medical doctor and philosopher and a former member of the Danish Council of Ethics. He is the former President of the European Society for Philosophy of Medicine and Health Care and former Editor in Chief of the *Journal of Medical Ethics*. He currently edits the journal *Clinical Ethics*.

Professor Richard A.L. Jones

Richard Jones is Pro-Vice-Chancellor for Research and Innovation at the University of Sheffield, is an experimental physicist whose own research concentrates on the properties of macromolecules at surfaces and interfaces. In his work in nanotechnology he is interested in learning from the principles used by cell biology to create synthetic, functional nanodevices. Professor Jones has also developed

a more general interest in nanotechnology and its potential impact on society, and has been extensively involved in public engagement around nanotechnology.

Professor Eli Keshavarz-Moore

Eli Keshavarz-Moore is Professor of Bioprocess Science and Enterprise at University College London. Her research interest is in the bioprocessing of complex macromolecules with therapeutic promise including fusion proteins, antibody fragments (monoclonal and polyclonal), artificial chromosomes and phages; and cells including microbial, mammalian and fungal systems as well as transgenic materials. She is one of the Principal Investigators in the Innovative Manufacturing Research Centre in Bioprocessing. Since 2000, Professor Keshavarz-Moore has led the development and implementation of innovative enterprise training and commercialisation of research opportunities at the bioprocessing/life sciences interface including a leadership programme for Senior Executives in the Bioscience industries.

Professor Noel Sharkey

Noel Sharkey is Professor of Artificial Intelligence and Robotics and Professor of Public Engagement at the University of Sheffield (Department of Computer Science). He has moved freely across academic disciplines, lecturing in engineering, philosophy, psychology, cognitive science, linguistics, artificial intelligence, computer science and robotics as well as lecturing extensively to the public, policy makers and the military. Noel's core research interest is now in the ethical application of robotics and AI in areas such as military, child care, elder care, policing, telepresence, transport and medicine. He is currently a Leverhulme Research Fellow for an ethical and technical appraisal of Robots on the Battlefield.

Professor Andrew Stirling

Andy Stirling is Professor of Science and Technology Policy and Research Director at SPRU (Science and Technology Policy Research) at the University of Sussex. He has a background in natural and social science, working formerly as an archaeologist, then a disarmament and environment activist. For 20 years, he has been an interdisciplinary researcher and policy adviser, focusing on challenges in the governance of science, technology and innovation. He has published widely on these issues and served on several public advisory bodies in the UK and EU.

Professor Patrick Sturgis

Patrick Sturgis is Professor of Research Methodology at the University of Southampton and Director of the ESRC National Centre for Research Methods. He is Principal Investigator of the Wellcome Trust Monitor study and President of the European Survey Research Association. His main research interests are in the areas of survey and statistical methods, public opinion and political behaviour, particularly regarding social cohesion and trust and public attitudes to science and technology.

Professor Andrew Tylecote

Andrew Tylecote is Emeritus Professor of the Economics and Management of Technological Change at the University of Sheffield. His background extends across the social sciences, and his research has ranged widely around the broad question: how do social and economic institutions affect technological change and economic development? He has been Treasurer of the European Association for Evolutionary Political Economy, and Visiting Professor at Tsinghua and Zhejiang universities, China. He was joint winner of the Myrdal Prize for his book with Francesca Visintin on *Corporate governance, finance, and the technological advantage of nations* (Routledge, 2007).

Glossary

Emboldened, italicised entries are terms used in this report with a specific meaning. Other italicised words refer to entries found elsewhere in the glossary, except where they denote titles.

Ambiguity: lack of agreement about the implications, meanings or relative importance of a given range of possible outcomes (irrespective of the likelihood of their occurrence). Ambiguity reveals the association of different and possibly incompatible meanings and values with the practices, products and consequences of biotechnologies.

Angel investor: a wealthy individual who invests in new businesses in return for pre-agreed financial return. Angel investors differ from venture capitalists in that the capital invested is usually owned by the investor. They sometimes operate collectively.

Antisense: a field of research within biomedical science focusing on preventing the progression of disease by making inactive the genes responsible. It involves introducing a strand of ribonucleic acid with a molecular composition that binds to genes identified as responsible for replication of disease in order to suppress their expression.

Asbestos: naturally occurring, fine mineral fibres which are highly heat-resistant and used in brake linings thermal insulation, fire resistant fabrics, (asbestos) cement, etc. Due to the major health hazards of the loose fibres and dust, its usage is now prohibited for some applications.

Avian flu: a naturally occurring genus of the influenza virus that is maintained in wild birds but also affects commercial and pet birds and can (rarely) infect mammals. There are multiple sub-types of the influenza A virus which can be divided into viruses of high and low levels of harmfulness. It is difficult for avian influenza viruses to infect humans but in 1997 the highly-pathogenic influenza A virus sub-type H5N1 emerged in Hong Kong and transmitted to humans, in some cases fatally.

Bioart: the creation of artworks from biological material including genetically modified organisms and artefacts.

Biodiversity: the genetic, taxonomic and ecosystem variety in the living organisms of a given area, environment, ecosystem or planet.

Bioeconomy: economic activity that is fuelled by research and innovation in the biological sciences.

Bioethics: a branch of *ethics*. Since the 1970s the term has been used to refer to the study of ethical issues arising from the biological and medical sciences.

Bioinformatics: a scientific discipline concerned with biological data, specifically the storage, transmission, retrieval and analysis of such data.

Bioreactor: an artificial device for the purpose of processing cells (or cell components) into desired products. This includes organisms modified to produce particular substances that they would not otherwise be able to produce. See *pharming*.

Bioremediation: the use of living organisms to absorb pollutants (usually in soil or water) in order to decontaminate a particular environment.

Biosafety: the safe handling and containment of infectious microorganisms and hazardous biological materials, applicable to humans, animals and the environment.

Biosecurity: securing biological materials in the context of military and national security risks. More generally, biosecurity can be understood as the protection of living organisms from harmful effects brought about by other species, especially the transmission of disease, although there is no single accepted definition of the term.

Biotechnology wager: the idea that in order for more people to enjoy longer, healthier, richer and more comfortable lives, it is as if society has – collectively – made a wager on the technologies of the future supplying the means continuously to outrun the costs of consumption and growth.

Bricolage: a word of French origin meaning the assembly of an artefact or the solution to a practical problem using whatever resources are at hand. The term has slightly different meanings across disciplines. In philosophy, the term is associated in particular with the work of Claude Lévi-Strauss, to describe a form of thought that arrives at solutions using multiple, sometimes unrelated, methods and concepts. In biology, it occurs in the metaphor of evolutionary processes as “a tinkerer, engaged in piecemeal construction.”⁷⁰⁷

Chimera: an animal comprised of whole cells from two or more different organisms.

Chlorofluorocarbons (CFCs): compounds consisting of ethane or methane with some or all of the hydrogen replaced by fluorine and chlorine. Used as refrigerants but their usage is now depreciated because they destroy atmospheric ozone and thus contribute to the greenhouse effect.

Citation impact: academic citations (references) used as a measure of usage and impact. Can apply to individuals, organisations or pieces of work. (See also *field weighted citation impact*.)

Clinical trial: a way of testing the efficacy of a treatment or a hypothesis related to the cause of a disease. ‘Phase 1’ trials evaluate safety and dose of a prospective treatment. ‘Phase 2’ trials evaluate effectiveness. ‘Phase 3’ trials confirm effectiveness and safety in preparation for wide-scale use.

Collingridge dilemma: a problem associated with the English social philosopher David Collingridge who suggested that attempting to control a technology is difficult because during its early stages, when it can be controlled, not enough can be known about its harmful social consequences to warrant controlling its development; but by the time these consequences are apparent, control has become costly and slow.

Consumer surplus: the excess of the benefit a consumer gains from the purchase of a good over the amount paid for the good. Can be measured by the by the area below the demand curve but above the price. (See also *producer surplus*.)

Defense Advanced Research Projects Agency (DARPA): an agency of the US Department of Defence tasked with maintaining the technological superiority of the US military and preventing ‘technological surprise’ from harming the national security of the US.

DIY biology/‘Do it yourself’ biology): ‘amateur’ individuals or groups undertaking or initiating biological experiments, processes or activities with little or no professional or institutional affiliation or oversight. Often performed as a hobby.

DNA: deoxyribonucleic acid; the chemical that carries a person’s genetic information. Most cells of a person’s body contain a complete copy of that information. A DNA molecule consists of a long chain of units called nucleotides or ‘bases’. There are four sorts of nucleotides: guanine, adenine, thymine, and cytosine.

Dual-use: a term applied to the tangible and intangible features of a technology that enable it to be applied to both hostile and peaceful ends with no, or only minor, modifications.

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

⁷⁰⁷ Wilkins AS (2007) Between “design” and “bricolage”: genetic networks, levels of selection, and adaptive evolution *Proceedings of the National Academy of Science* **104**: 8590-6.

Field-weighted citation impact: an indicator of quality that adjusts for differing citation practices in different subject fields and therefore of the different subject emphases of comparator countries. (See also *citation impact*.)

Frame: broadly, a background of knowledge, beliefs and values that give a particular significance to different possible objects of contemplation. The concept of a ‘frame’ has different meanings across various disciplines including sociology, communication studies and cognitive psychology. In particular, the concept is associated with the sociologist Erving Goffman and his book *Frame analysis* in which he defined a frame as “definitions of a situation...built up in accordance with principles of organization which govern events – at least social ones – and out subjective involvement with them”.

Framework programme(s): the ‘Framework Programmes for Research and Technological Development’ are multi-year EU funding programmes. As of 2012, there have been seven such programmes. Framework seven is due to end in 2013. Research priorities vary between programmes.

Free rider: those who partake of the benefits of some cooperative enterprise without contributing to it.

Full-cost accounting: an accounting technique that recognises multiple types of ‘value’, including financial, social and environmental.

Gene therapy: treating disease caused by faulty genes or gene function by the introduction of new therapeutic genes directly into the patient’s cells by means of vectors, such as modified viruses.

Gene: the fundamental unit of inheritance. A gene is an ordered sequence of nucleotides located in a particular position on a certain chromosome that encodes a specific functional product (i.e. a protein or RNA molecule).

Genetic modification: the direct introduction of specific characteristics by artificial transfer of functional genes into an organism.

Genome: the full complement of genetic material in the cells of an individual organism or species; the totality of the DNA sequences of an organism or organelle.

Green revolution: a range of practices and technologies (including chemical pesticides, fertilisers, irrigation and plant breeding) that transformed agricultural food production in the decades following the 1940s, in particular through technology transfer to developing countries.

Gross domestic product (GDP): the total market value of all goods and services produced within a country in a specific period of time.

Gross national product (GNP): the total market value of all goods and services produced by the residents of a country in a specific period of time, including value produced by nationals working abroad and excluding value produced by foreign nationals working in the relevant host country.

H5N1: see *avian flu*.

Haber-Bosch process: a process of fixing nitrogen, in which the nitrogen is made to combine with hydrogen under influence of high temperature, high pressure and a catalyst for the purposes of creating ammonia, which is then usually used in the production of fertiliser.

Health impact fund: a method proposed as a way of remedying the perceived failure of the global pharmaceutical development and distribution system to attend properly to the needs of certain subpopulations. It is designed to reward pharmaceutical firms that develop drugs mainly for use in developing countries.

Higher Education Funding Council for England (HEFCE): a non-departmental public body of the Department for Business, Innovation and Skills in England, responsible for distributing public money for higher education to universities and colleges in England, for the purposes of research, education and related activities; HEFCE’s focus is on funding research infrastructure. Compare to the *research councils*, which provide funding for specific research projects and programmes.

Human Genome Project: a 13-year international project established in 1990 to coordinate the sequencing of the 2.85 billion nucleotides that make up human DNA. The first draft was published in 2001.

iGEM Foundation: 'International Genetically Engineered Machine Foundation'; an organisation dedicated to education and competition, advancement of synthetic biology, and the development of open community and collaboration.

In silico: a term used to describe bioscientific experiments carried out using a computer (i.e. on a silicon chip).

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 with or injected with sperm. A resulting embryo may then be transferred to a woman's uterus with the intention of establishing a pregnancy.

Innovation and Knowledge Centres: specialised centres of UK scientific excellence, granted five years' funding from a UK research council or the Technology Strategy Board in order to accelerate and promote business exploitation of an emerging research and technology field.

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

Knowledge economy: an economy the focus of which is information rather than physical products or processes (mining or manufacturing, for example). This may be a focus on the production of information or a focus on physical production or processes based on particular types of information.

Lock-in: the idea that specific technological pathways, although not inevitable in advance, once embarked upon become progressively difficult and costly to escape.

Monoclonal antibody: antibody produced by a single clone of cells or a cell line derived from a single cell. Such antibodies are all identical and have unique amino acid sequences.

Nanomedicine: the use of nanotechnological techniques or materials for medicinal purposes.

Nanotechnology: the 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).

National Health Service: the name applied to the publicly-funded healthcare services that operate in the constituent countries of the UK.

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.

Opportunity cost: the cost of something in terms of an opportunity foregone when it is chosen, i.e. the benefits that could have been obtained by choosing the best alternative opportunity. Sometimes used loosely to describe situations where the characteristic of *ambiguity* can mean that opportunities foregone may actually be more highly valued by some subpopulations within society, despite being more highly valued by others who may have the power to select them.

Optical tweezers: a beam of light that exerts force in the piconewton range that is sufficient to move small organelles around under a microscope or to measure the forces that motor molecules are exerting.

Orphan drug: a pharmaceutical developed and produced for a patient population that too small to be considered economically feasible to provide for under standard pharmaceutical industry business models.

Patent: the right, granted by a government, to exclude others from making, using or selling an invention.

Path dependency: a concept that describes how prior contingent choices constrain subsequent ranges of options. It was primarily developed within the field of economics to explain why certain technological 'paths' have been taken in preference to others. It is also used in a number of other disciplines, such as the political and social sciences, being adapted to the relevant context.

Personalised medicine: a concept that reflects a confluence of different scientific, technological and social disciplines and approaches. It has a number of different meanings, but among these is the tailoring of medicine to the biological characteristics of particular patients or patient groups (pharmacogenetics, stratified medicine). The basic enabling technology for personalised medicine is molecular diagnostics.

Pharming: the use of genetically modified animals as *bioreactors* to produce substances beneficial to humans, such as insulin for the treatment of diabetes and vaccines, which may be extracted, for example, from the animals' milk.

Phase 1/2/3 clinical trial: see *Clinical trial*.

Pluripotent: the capacity for some cells to differentiate into many, but not all, final differentiated cell types of an organism. Compare to multi- and toti- potent cells (respectively, the potential to give rise to a variety of limited cell types (the result based on environmental cues) and the ability to divide into all differentiated cell types of the relevant organism).

Polyketides: a class of drugs with a variety of uses, such as the production of antibiotics and insecticides.

Precautionary principle/approach: an approach often implemented in the field of technology regulation that arises from realisations about the limits of narrow, risk-based approaches when operating under conditions of uncertainty and ambiguity. Originally articulated in Principle 15 of the 1992 Rio Declaration on Environment and Development as: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." It is subject to disputed interpretation.

Pre-implantation genetic testing/diagnosis: a technique in which genetic testing of an *in vitro* fertilised embryo is carried out before the decision to implant the embryo is taken.

Producer surplus: the value of total sales revenue going to producers over the area above the supply curve and below the price for a good; the benefit that producers accrue by selling a product for an amount more than the lowest cost at which they would be prepared to sell that product. (See also *consumer surplus*.)

Public engagement: engagement between those accountable for a given range of practical decisions and those who have a 'public' interest in their outcomes.

Public ethics: a concept of ethics used in this report broadly reflecting both a general reorientation away from an individualistic ethical tradition and recognition of an inherent public interest in biotechnologies. 'Public ethics' focuses on moral action that has broad social implications and is concerned with the formation of the context within which public decisions are made and by which they are framed (rather than the inclusion of a consideration of ethical implications as an element of the process of policy development and governance.)

Public good: a good that is non-rivalrous or non-excludable, or both. A good is non-rivalrous if my use of it does not in any way reduce the amount of it available for you to use. A good is non-excludable if it cannot be made available to you without also making it available to me and any number of others who might also wish to enjoy it.

Public sphere: a term which can be (broadly) understood to describe the social, intellectual and spatial phenomena of private actors joining in open, public discussion of societal issues. Primarily based on the work of Jürgen Habermas, in particular the book *The structural transformation of the public sphere*.

Quality-adjusted life year (QUALY): a method used to compare different pharmaceuticals and measure their clinical effectiveness. The UK National Institute for Health and Clinical Excellence (NICE) website notes that it is intended to “[give] an idea of how many extra months or years of life of a reasonable quality a person might gain as a result of treatment”. NICE use the output of a QUALY measurement as a way of calculating cost-benefit.

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 (R&D): work directed towards the innovation, introduction and improvement of products and processes. The term is used primarily in the private sector.

Research council(s): the UK’s research councils are publicly funded agencies responsible for investing public money in research in the UK. They provide funds for specific research projects and programmes. Compare to the *Higher Education Council for England*, which provides funds focused more on research infrastructure.

Research Excellence Framework (REF): a system for assessing the quality of research in UK higher education institutions.

Research intensity: a nation’s gross expenditure on R&D measured as a share of that nation’s *gross domestic product*.

Responsible innovation: governance of science and innovation that includes considerations of risk and regulation and the incorporation a collective approach to defining how science and innovation should influence the future; it considers questions of anticipation, reflexivity, inclusion and responsiveness.

Ribosome: a cell organelle made of ribosomal RNA and protein. It is the main site of biological protein synthesis.

RNA: ribonucleic acid, a molecule similar in structure to *DNA*. It is the main agent for transferring information from DNA to the protein-synthesizing machinery of cells, but can also hold genetic information (as it does in the case of viruses).

RNAi: ribonucleic acid interference; the blocking of gene expression by disrupting the translation of messenger *RNA* into proteins. When performed through artificial means it is often used to study gene function. The blocking of gene function also has therapeutic potential.

Semiconductor: an element or compound having higher resistivity than a conductor but lower resistivity than an insulator. Semiconductor materials are the basis of diodes, transistors, thyristors, photodiodes and all integrated circuits (‘silicon chips’).

Sequencing: procedure for determining the sequence of nucleic acid or protein.

Sociotechnical imaginary: the way science and technology influence collective visions of good and attainable futures.

Spin-out/spin-off: either a subsidiary of a ‘parent’ organisation or an entirely new, independent organisation that has split-off from its parent. Commonly occurs in the context of a small, independent spin-out company formed by splitting off from a larger, parent, academic organisation (such as a university) for the purpose of profitable commercialisation of a technology developed originally within an academic setting.

Stem cells: non-specialised cells, which can divide indefinitely to 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.

Sustainability: as elucidated by the Brundtland Commission, “meeting the needs of the present without compromising the ability of future generations to meet their own needs.”

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.

System effects: the interdependency of elements within systems acting as an exponent of small, local effects, potentially leading to large-scale changes.

Technological determinism: the potential of a technology to determine the horizon of possibilities for society in a non-trivial way. That is, that the technologies in use exert a dominant or shaping force on society and social organisation.

Technological paradigm: a concept developed in technology studies literature to support evolutionary explanations of both continuous and discontinuous technical change.

Technological singularity/‘the singularity’: a notion expressing the overtaking of human intelligence by intelligence not of solely biological origin.

Technological trajectory: a concept closely related to that of the ‘*technological paradigm*’. Technological trajectories have been described as being the direction of technical advance within a certain technological paradigm; the ‘pattern’ of the normal technological progression inherent in the concept of technological paradigms.

Technology ‘roadmapping’: a process during which an attempt is made to identify, plan and record the requirements for goal-orientated technology development. May be used to articulate and promote collective visions for technology development.

Technoscientific imaginary: a label for the ways in which attitudes to prospective technologies are construed in terms of the kind of world that technological developments may bring about. These commonly incorporate features such as longevity, health into old age, free electricity/power, inexpensive consumption, etc., and corresponding dystopias, such as decimation by mutant pandemic viruses or the emergence of a ‘genetic underclass’.

The Enlightenment: a Western intellectual movement of the late 17th and 18th Centuries emphasising reason and individualism rather than tradition.

Tissue engineering: a technique for addressing tissue and organ failure by implanting natural, synthetic, or semisynthetic tissue and organ mimics that are fully functional from the start, or that grow into the required functionality.⁷⁰⁸

Transformative potential: the capacity that some emerging biotechnologies may have to transform or displace existing social relations, practices and modes of production, or create new capabilities and

⁷⁰⁸ See: Nature Biotechnology editorial (2000) Tissue engineering *Nature Biotechnology* **18**, IT56-IT58.

opportunities that did not previously exist (or may not even have been imagined). These outcomes might be entirely unexpected or unsought.

Transhumanism: an ideology that valorises the transformation of the human condition through technologies, for example, to promote life extension or cognitive and physical enhancement.

Uncertainty: an inescapable lack of knowledge about the range of possible outcomes or about the likelihood that any particular outcome will in fact occur. This seriously limits the possibility of accurately forecasting the consequences of decisions with regard to biotechnologies (positive or negative) and similarly limits the effectiveness of prospective efforts to control these outcomes.

Venture capital: capital whose owners are willing to invest in new or small businesses, where the risk of losing is high, usually in exchange for correspondingly high returns.

Xenobiology: a field of study which attempts to make a biology that is altogether different from that which is found in nature, such as attempting to use different kinds of nucleic acid, for example 'xenonucleic acid' (XNA) as opposed to the familiar *RNA* or *DNA*.

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

The definitions above are derived from a number of sources. Significant, uncited, sources include several previous Nuffield Council reports; *Chambers dictionary of science and technology* (2007); *Oxford dictionary of philosophy*, 2nd edition (2008); *Taber's cyclopedic medical dictionary*, 21st edition (2009); *Oxford dictionary of sociology*, 3rd edition (2009); *Concise Oxford English dictionary*, 12th edition (2011); and, *Oxford dictionary of economics*, 4th edition (2012).

List of abbreviations

AEBC	Agriculture and Environment Biotechnology Commission
BBSRC	Biotechnology and Biological Sciences Research Council
BIS	(Department of) Business, Innovation and Skills
BIVDA	British In Vitro Diagnostics Association
BPAA	Best previously available alternative(s)
BPF	Big pharmaceutical firm
DBF	Dedicated biotechnology firm
Defra	Department for Environment, Food and Rural Affairs
DNA	Deoxyribonucleic acid
DTI	Department of Trade and Industry
EFSA	European Food Safety Authority
EPSR	Engineering and Physical Sciences Research Council
ESBAC	Emerging Science and Bioethics Advisory Committee
ESRC	Economic and Social Research Council
FDA	(US) Food and Drug Administration
FET	Future Emerging Technologies
FSA	Food Standards Agency
GDP	Gross domestic product
GM	Genetically modified
GMO	Genetically modified organism
GNP	Gross national product
GSK	GlaxoSmithKline
HEFCE	Higher Education Funding Council for England
hESC	Human embryonic stem cell
HFEA	Human Fertilisation and Embryology Authority
HGC	Human Genetics Commission
HGP	Human Genome Project

HI	Health impact
HIF	Health impact fund
HIP	Health impact payment
ICT	Information and communications technologies
IPR	Intellectual property rights
IT	Information technologies
ITRS	International Technology Roadmap for Semiconductors
IVF	<i>In vitro</i> fertilisation
LMB	(Cambridge) Laboratory of Molecular Biology
MHRA	Medicines and Healthcare products Regulatory Agency
MoD	Ministry of Defence
MRC	Medical Research Council
NAS	New active substance
NEST	New and Emerging Science and Technologies
NHS	National Health Service
NSABB	(US) National Science Advisory Board for Biosecurity
OECD	Organisation for Economic Co-operation and Development
PPP	Public private partnerships
R&D	Research and development
REF	Research Excellence Framework
RNA	Ribonucleic acid
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TSB	Technology Strategy Board
WHO	World Health Organization