NUFFIELD COUNCIL ON BIOETHICS

Emerging biotechnologies: technology, choice and the public good

Consultation summary

January 2013

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Introduction and summary of process

A public consultation was held between April and July 2011 as part of the project that led to the publication of the Nuffield Council on Bioethics' report Emerging biotechnologies: technology, choice and the public good. A consultation document consisting of 17 questions and associated, relevant background information was prepared by the Working Party. Respondents were encouraged to answer as many or as few questions as they wished. The consultation document is available on the website of the Nuffield Council on Bioethics.

The consultation document was disseminated to a variety of individuals and organisations via a targeted mailout as well as publication on the Council's website. Eighty four responses were received in total, of which 48 were submitted by individuals and 36 on behalf of organisations. Responses to the consultation informed the deliberations of the Working Party both through the discussion and analysis of individual responses and the consideration of more general themes identified across the totality of the responses.

The text below summarises some of the views and observations raised by respondents to the consultation. However, it is not intended to be a quantitative survey; responses were not taken from a representative sample, and should not be treated as such. Copies of individual responses have been made available on the Council's website in those instances where the Council has permission from respondents to do so. A number of respondents gave permission to use the content of their responses but requested that their submissions be kept anonymous within the text.

Where relevant to the question or the responses provided, the various positions, arguments and conclusions of the Working Party have been noted briefly.

List of questions

1 How would you define an 'emerging technology' and an 'emerging biotechnology'? How have these terms been used by others?

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6 Are there examples where internationalisation or globalisation of research, markets and regulation have influenced the development of emerging biotechnologies?

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8 Are there ethical of 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?

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?

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?

13 What roles have 'risk' and 'precaution' playing 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?

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?

Emerging technologies

Question 1: How would you define an 'emerging technology' and an 'emerging biotechnology'? How have these terms been used by others?

Responses to this question were split mainly into a few general categories: examples of technologies that respondents thought fell under the term 'emerging biotechnology'; suggestions for how to define 'emerging technology' and 'emerging biotechnology'; and, whether such definitions were helpful or even possible. (A list of example technologies given by respondents can be found at the end of this section.)

There was significant variation between given definitions. Many respondents focused on the nature of the term 'emerging' as it applies to both technology and biotechnology, although some did aim to explain what separated 'biotechnologies' from other technologies. Some respondents stated that there are two main ways of construing 'biotechnology': technology concerned with the manipulation of, or intervention in, biological materials or processes; alternatively, any technology that has an impact on such materials or processes.[1] Others fell firmly on one side or the other of this division, but did not explicitly recognise the alternative. For example, some felt that biotechnologies were those with a biological basis, use or application[2] or those capable of manipulating, developing or enhancing life.[3] Others felt that a relationship to the fields of biology or healthcare was sufficient.[4] One noted that 'biotechnology' had "become synonymous with genetic modification and genetically modified (GM) crops".[5] The use and meaning of the term 'biotechnology' was considered in detail by the Working Party and is discussed in Chapters 1 and 2 of the report;[6] the Working Party took the view that a biotechnology can be considered the productive conjunction of knowledge, practices, products and applications.

There were some common themes when discussing the meaning of 'emerging' as it relates to technology. A common element was that of novelty or 'newness'.[7] However, it was emphasised by some that such novelty was not necessarily restricted to, for example, new scientific knowledge; novelty could also be a new application of a pre-existing technology.[8] One respondent specifically cautioned against focusing on novelty in this context.[9]

The response from Egenis, University of Exeter, noted that technologies might be considered to be emerging for a number of reasons, beyond and in addition to a conventional understanding relating to novelty: the technologies stalled at some point in the innovation cycle (for example, GM crops); they remain contested public goods despite their presence on the market or in clinical practice (regenerative medicine, for example); they are established technologies that have moved into new and contested domains (nutrigenomics); or, they are in an early stage in translation from scientific demonstration/discovery to technical feasibility.[10]Other notable aspects of definitions provided by respondents included intent (that of "benefiting life"),[11] uncertainty and unpredictability,[12] the effect that such technologies might have (e.g. new social and ethical concerns or the exposition of varying perspectives and worldviews in different stakeholders),[13] immaturity (specifically in relation to the development cycle of a technology and the point at which a new technology might be "supported by corporate investment"),[14] difficulty of governance,[15]

1 Prof. Maude Phipps, Jeffrey Cheah School of Medicine & Health Sciences, Monash University; Sal Restivo & Sabrina Weiss, Rensselaer Polytechnic Institute .
2 Anonymous respondent; UK Science and Innovation Network (Canada).
3 The Church in Wales.
4 Anonymous respondent; LY.
5 Mr K R Coleman.
6 See paragraphs 1.13 and 2.1-2.5. Paragraph 2.6-2.27 provides a list and some background information to some example technologies the Working Party considered relevant to the report.
7 Anonymous respondents; Ines Violeta Ortega Garcìa; Professor Raphael Cohen-Almagor, University of Hull; RCOphth (submission from Professor Dua, President of RCOphth); Sal Restivo & Sabrina Weiss, Rensselaer Polytechnic Institute; The Church in Wales; UK Science and Innovation Network - Switzerland (response compiled by Gaby Bloem); Yutaka Hishiyama.
8 RCOphth (submission from Professor Dua, President of RCOphth); RSPCA; UK Science and Innovation Network - Switzerland (response compiled by Gaby Bloem).
9 RCOphth (submission from Professor Dua, President of RCOphth).
10 Egenis, University of Exeter.
11 RCOphth (submission from Professor Dua, President of RCOphth).
12 ESRC Innogen Centre; Science, Culture and the Law (SCuLE), University of Exeter School of Law.
13 Hilary Sutcliffe, MATTER; Professor Nick Pidgeon, Cardiff University; Yutaka Hishiyama.
14 The Royal Academy of Engineering.
15 Go Yoshizawa, University of Tokyo.

and the assertion that an emerging biotechnology need not be controversial and may sometimes be merely "mundane".[16]

Some respondents were sceptical about the possibility of providing a cogent definition and, even if such a definition could be provided, whether it would be useful to do so. One respondent argued that "all technologies represent developments of earlier ones" and that representing a technology as entirely new could offer "an opportunity for forces antipathetic to novelty in technology to oppose any new developments".[17]The ESRC Innogen Centre noted that "the terms 'emerging technology' and 'emerging biotechnology' tell us very little". Others noted that they were "not in favour of a precise definition",[18] that they were "increasingly finding the term unhelpful"[19] and that the phrase 'emerging technology' was "distinctly confusing".[20] One respondent did not attempt a definition on the basis that emerging biotechnologies "have no singular shape or form".[21]

The nature of the concept of 'emergence' – i.e. its attendant properties and consequences – was one of the primary issues considered by the Working Party, and was addressed generally by Part 1 of the report, in particular paragraphs 1.13-1.15 and the whole of Chapter 3. The relevant paragraphs in Chapter 1 noted that the Working Party adopted the position that 'emergence' can be thought of as a process involving an 'assemblage' of the constituent elements of a biotechnology (knowledge, practices, products and applications, as mentioned above) that is subject to a number of conditions and externalities; such a process was not considered to be necessarily linear. The latter part of Chapter 1 of the report explored in detail the idea of contingency and how emergence can be understood as a branching process. Chapter 2 examined in what technological developments the Working Party was interested; many of these overlapped with the list below.

Technologies cited by consultation respondents as examples of emerging biotechnologies

- ART
- Assisted suicide technology
- Biofuels
- Bioinformatics
- Cell-free fetal nucleic acid technologies
- Cloned animals
- Digital technologies, such as smart implants
- DNA databanks
- DNA fingerprinting
- Environmental bioremediation
- Food irradiation
- Gene therapy
- Genetic engineering
- Genetically modified animals
- Genomic medicine
- Genomics
- Geoengineering
- Human enhancement technologies
- Hybrid embryos
- Induced mutagenesis/genomics in plant breeding
- Microbial metagenomic profiling
- Nanomedicine
- Nanotechnology
- Neurobiology
- New therapeutic technologies
- Nutrigenomics
- Plant- and microbial-made pharmaceuticals
- Regenerative medicine
- Reproductive cloning
- Site directed mutagenesis
- Stem cells therapies
- Synthetic biology
- Tissue engineering
- Xenotransplantation

[16] Professor Nick Pidgeon, Cardiff University.
[17] Professor Vivian Moses.
[18] Professor Derek Burke.
[19] Hilary Sutcliffe, MATTER.
[20] Mr K R Coleman.
[21] Cesagen (ESRC Centre for Economic and Social Aspects of Genomics).

Question 2: Do you think that there are features that are essential or common to emerging biotechnologies? (If so, please indicate what you think these are.)

A number of respondents believed that there are particular features common to emerging biotechnologies. However, some did not regard attempts to identify essential or common features as a "useful way to proceed",[22] and others felt that it was "difficult to posit – in the abstract – 'essential' or 'common' features across such a broad category".[23] One noted that there are common, but not essential, features that could be identified.[24]

There was variation in the suggestions provided by those who believed that there were commonalities to be identified. However, the suggestions made by respondents can be separated into two board categories:

1) qualities inherent in the technologies themselves; and
2) those features that relate to the outcome or influence the technology.

Representative examples under the first category include multidisciplinarity,[25] the "manipulation of processes that until now were only natural",[26] impact on human welfare,[27] rapid development,[28] the sophisticated – but often "immature"[29] – knowledge of science in general and biological systems specifically,[30] the involvement of multinational corporations in the development of the relevant technology,[31] and the unsuitability of the technology for use on a large scale.[32]

The second category included: the generation of controversy or excitement;[33] the potential for 'breakthroughs' in certain areas of research;[34] improved health outcomes;[35] influences on justice (e.g. the high cost of the technologies and their potential to widen the gap between developed and developing countries and between the rich and the poor);[36] influences on, or redefinition of, the understanding of life.[37]

Some properties were identified by multiple respondents: inter- and multi-disciplinarity, with regard to both the genesis and study of emerging biotechnologies, was considered by several respondents to be key;[38] others felt that risk and uncertainty, especially the understanding of both by the public, were important issues;[39] of concern for some was the understanding of potential applications, and the hyperbole that sometimes surrounds potentialities.[40]

Chapter 3 of the report outlined three distinctive characteristics the Working Party argued make governance of emerging biotechnologies especially problematic:

- uncertainty (an inescapable lack of knowledge about the range of possible outcomes or about the likelihood that any particular outcome will in fact occur);
- ambiguity (a lack of agreement about the implications, meanings or relative importance of a given range of possible outcomes, irrespective of the likelihood of their occurrence); and
- 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 opportunities that did not previously exist, or may not even have been imagined.)

22 Professor Derek Burke.
23 Anonymous respondent.
24 Dr Sara Fovargue, Law School, Lancaster University.
25 Science and Innovation Network - India.
26 Ines Violeta Ortega Garcìa.
27 Go Yoshizawa; Science and Innovation Network - India; University of Tokyo; The Church in Wales.
28 Anonymous respondent.
29 Cesagen (ESRC Centre for Economic and Social Aspects of Genomics).
30 Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain.
31 Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain.
32 Leicester Medical Students Group 1.
33 Anonymous respondent.
34 Anonymous respondent.
35 Anonymous respondent.
36 Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain.
37 Science, Culture and the Law (SCuLE), University of Exeter School of Law.
38 Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague; Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain; Professor Bonnie Steinbock.
39 Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague; Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain.
40 Anonymous respondent; RCOphth (submission from Professor Dua, President of RCOphth).

Question 3: What currently emerging biotechnologies do you consider have the most important implications ethically, socially and legally?

The technologies respondents mentioned as having important implications matched closely those listed under question one. One respondent noted that *all* emerging biotechnologies have ethical, social and legal implications,[41] another that all technologies have ethical implications.[42] It was also argued that the importance of a technology is contextual: for example, in the developing world the most important emerging biotechnology is likely to be agricultural biotechnology.[43] Some of the main technologies specifically mentioned under this question included:

- assistive reproductive technologies (ART);[44]
- autonomous systems;[45]
- cloned animals;[46]
- gene therapy;[47]
- genomics;[48]
- GM crops;[49]
- human enhancement;[50]
- human-animal chimeras;[51]
- nanotechnology;[52]
- neurobiology;[53]
- regenerative medicine;[54]
- synthetic biology; and[55]
- xenotransplantation.[56]

GM crops in particular were mentioned by a considerable number of respondents. However, other respondents argued (sometimes in answer to other questions) that genetic modification should not be considered an emerging technology,[57] or at least only as 'emerging' in some regions.[58]

Some respondents gave substantial explanations as to why they believed a specific technology raised particular implications, and the nature and content of such explanations varied between respondents even where the same technology was at issue. It was pointed out that any social, ethical or legal implications raised by novel technologies were not, by definition, of concern and may in fact reduce existing hazards;[59] i.e. that 'implications' is a value-neutral term. One respondent argued that there were no emerging biotechnologies that should be considered to have important ethical, legal or social implications.[60]

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41 Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague.
42 Professor Vivian Moses.
43 Anonymous respondent.
44 Anonymous respondent; Ines Violeta Ortega Garcìa; Jayapal Azariah Founder President, All India Bioethics Association.
45 The Royal Academy of Engineering.
46 RSPCA.
47 Anonymous respondent; Professor Raphael Cohen-Almagor, University of Hull.
48 Anonymous respondents; Professor Sir David Weatherall.
49 Anonymous respondents; Federal Ethics Committee on Non-Human Biotechnology (ECNH); GeneWatch UK; Ines Violeta Ortega Garcìa; Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain; Mr K R Coleman; Professor Derek Burke; RSPCA; The Church in Wales; UK Science and Innovation Network - Switzerland (response compiled by Gaby Bloem); UK Science and Innovation Network (Canada).
50 Professor Kevin Warwick; UK Science and Innovation Network - Switzerland (response compiled by Gaby Bloem); Hilary Sutcliffe, MATTER; Anonymous respondent; Research Councils UK.
51 Sal Restivo & Sabrina Weiss, Rensselaer Polytechnic Institute.
52 Professor Nick Pidgeon, Cardiff University; UK Science and Innovation Network - Switzerland (response compiled by Gaby Bloem); RSPCA; Anonymous respondent; Anonymous respondent; Federal Ethics Committee on Non-Human Biotechnology (ECNH); Sal Restivo & Sabrina Weiss, Rensselaer Polytechnic Institute; Science and Innovation Network - India; UK Science and Innovation Network (Canada); The Church in Wales; Professor Sir David Weatherall.
53 Research Councils UK.
54 Medical Ethics Alliance; Science and Innovation Network - India; Go Yoshizawa, University of Tokyo; The Church in Wales.
55 Research Councils UK; UK Science and Innovation Network - Switzerland (response compiled by Gaby Bloem); Dr Alan R Williamson; Hilary Sutcliffe, MATTER; Professor Nick Pidgeon, Cardiff University; Anonymous respondent; Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague; Anonymous respondent; Federal Ethics Committee on Non-Human Biotechnology (ECNH); Sal Restivo & Sabrina Weiss, Rensselaer Polytechnic Institute; Science and Innovation Network - India; Go Yoshizawa, University of Tokyo; Anonymous respondent.
56 Professor Raphael Cohen-Almagor, University of Hull; UK Science and Innovation Network - Switzerland (response compiled by Gaby Bloem); Dr Sara Fovargue, Law School, Lancaster University; Anonymous respondent.
57 Agricultural Biotechnology Council (abc).
58 Professor Derek Burke.
59 Sense about Science.
60 Prof. Maude Phipps, Jeffrey Cheah School of Medicine & Health Sciences, Monash University.

Cultural, international and historical context

Question 4: Are there examples where social, cultural and geographical factors have influenced the development of emerging biotechnologies (either in the past or currently)?

Some respondents noted that it was very rare for the factors mentioned in the question to *not* have an influence on the development of emerging biotechnologies.[61] One respondent focused more generally on the nature of the system by which technologies are developed, insofar as "the whole basis of R&D investment in biosciences and biotechnologies has been strongly influenced by a political commitment to building a new bioeconomy".[62]

A number of respondents felt that research into stem cell technology has been subject to significant influence by social and cultural factors: approaches to the technology were often sharply defined by geographic region. It was argued that in some cases this had resulted in research activity moving to countries not traditionally associated with high-technology research, such as Malaysia.[63] Although the influence on stem cell research by social and cultural factors was approached as a fact by most respondents who noted any such influence, one respondent cautioned against making these assumptions in the absence of hard evidence relating to "the comparative successes/failures of stem cell research" between the UK and the USA.[64]

Another commonly cited example was agricultural biotechnology generally (and GM crops specifically): one respondent argued that "Europe has abandoned agricultural biotechnology not only in its fields but in its laboratories and research programs for agriculture";[65] resistance to 'golden rice' was also cited.[66]

Other examples included:

- the cultural value of reproduction in Israel and the effect this has on the uptake ARTs in that country;[67]
- dissonance between traditional Polish cultural attitudes to the moral and legal status of the embryo and European Union legal instruments and their concomitant influence on the use and development of IVF and ARTs in Poland;[68]
- the influence on the development of reproductive technologies caused by women in some cultures waiting until later in life (than has sometimes traditionally been the case) to have children;[69]
- the physically "harsh environment" of Canada encouraging use of GM crops;[70]
- the general failure to develop particular pharmaceuticals or other high technology interventions for small populations or populations in poor countries due to lack of profitability in doing so;[71] and,
- the influence of political systems on research and development in general (from the point of view of one respondent, the restrictive nature of research in Soviet-era Czechoslovakia in comparison to the that conducted in the Czech Republic after the fall of the Berlin Wall).[72]

Some respondents questioned or noted underlying themes, rather than identifying specific technologies. Dr Sara Fovargue, for example, argued that "In most societies there appears to be a 'forward stampede' which advocates new biotechnologies" which could draw attention from "other, less technological, problems and solutions". Another respondent questioned whether there was a need for the kind of technologies under discussion.[73]

One respondent interpreted "influence" in terms of restriction or "getting in the way", and noted that, generally, the only relevant factor influencing the development of emerging biotechnologies was the availability of funding.[74]

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61 Anonymous respondents.
62 GeneWatch UK.
63 Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain; PHG Foundation; Cesagen (ESRC Centre for Economic and Social Aspects of Genomics); Anonymous respondents; Professor Sir David Weatherall.
64 Cesagen (ESRC Centre for Economic and Social Aspects of Genomics).
65 Drew L Kershen, Professor of Law (U.S.A.).
66 Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain; Drew L Kershen, Professor of Law (U.S.A.).
67 Anonymous respondent.
68 Science, Culture and the Law (SCuLE), University of Exeter School of Law.
69 The Church in Wales.
70 UK Science and Innovation Network (Canada).
71 RCOphth (submission from Professor Dua, President of RCOphth).
72 Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague.
73 Mr K R Coleman.
74 Hilary Sutcliffe, MATTER.

Question 5: Are there examples where social, cultural and geographical factors have influenced public acceptance or rejection of emerging biotechnologies?

The responses to this question to a large extent reflected those given to Question 4; some respondents provided a single response for both questions. It was again stated by one respondent that there are always social and cultural factors at issue when considering public acceptance or rejection,[75] in addition to any fears regarding, for example, health or safety.

Agricultural biotechnology, stem cells and attitudes to the moral and legal status of the embryo were common examples.[76]

There were notable comments regarding the process by which the 'public' accepts or rejects emerging biotechnologies. For example, the factors involved in making a technology appear more or less acceptable to the public were outlined by one respondent: "identifiable victims, invisible hazards, a technology not fully understood by scientists, a 'dread' outcome such as cancer, and distrust in authorities or promoters" could render a technology less attractive to the public; "visible benefits" were identified as the primary mitigating factor in these circumstances.[77]

It was also argued, in terms of medical biotechnologies at least, that "there is very little critique of what should be defined as 'progress'. It seems rather that the scientist's promise to find cures is enough".[78] This was particularly significant to the relevant respondent given their interpretation of the process by which such technologies are adopted, i.e. that medical scientists are presumed to be trying to find cures to diseases and, if some community groups dislike the methods by which this is done politicians will, in the absence of compelling data on which to base their decisions, overrule those groups on the assumed basis that "medical progress is good".[79]

The role of community groups and NGOs in relation to the public acceptance of GM crops was commented on by a number of respondents.[80] There was criticism of the manner in which some NGOs approached the issue of GM crops – one respondent described them as having an "inordinate and negative influence", and argued that they had manipulated public opinion against GM.[81]

Other examples of how social, cultural and geographical factors have influenced the acceptance or rejection of technologies included:

- the more ready acceptance of organ transplantation in the USA and UK in comparison to, for example, Germany, Japan and Malaysia due respectively to ongoing discussion regarding Nazi experimentation in the mid-20th century, traditional cultural beliefs regarding the heart and brain death, and religious beliefs regarding tissue of porcine origin, respectively;[82]
- low acceptance of preimplantation genetic diagnosis in Germany for similar reasons as above;[83] and
- different understandings of a 'right of access' to DNA data between the UK and the USA with regard to the uptake of direct-to-consumer genetic testing.[84]

[75] Professor Nick Pidgeon, Cardiff University.
[76] Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague; RCOphth (submission from Professor Dua, President of RCOphth); Anonymous respondent; Drew L Kershen, Professor of Law (U.S.A.); Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain; Ines Violeta Ortega Garcìa; Hilary Sutcliffe, MATTER; Science, Culture and the Law (SCuLE), University of Exeter School of Law; Anonymous respondent; Cesagen (ESRC Centre for Economic and Social Aspects of Genomics); Anonymous respondent; Sal Restivo & Sabrina Weiss, Rensselaer Polytechnic Institute; UK Science and Innovation Network (Canada).
[77] Professor Nick Pidgeon, Cardiff University.
[78] Anonymous respondent.
[79] Anonymous respondent.
[80] Drew L Kershen, Professor of Law (U.S.A.); Professor Nick Pidgeon, Cardiff University; Dr Christopher French.
[81] Drew L Kershen, Professor of Law (U.S.A.).
[82] Anonymous respondents; Prof. Maude Phipps, Jeffrey Cheah School of Medicine & Health Sciences, Monash University.
[83] Cesagen (ESRC Centre for Economic and Social Aspects of Genomics).
[84] GeneWatch UK.

Question 6: Are there examples where internationalisation or globalisation of research, markets and regulation have influenced the development of emerging biotechnologies?

A number of respondents agreed that internationalisation and globalisation of research, markets and regulations have influenced the development of emerging biotechnologies.[85] Technologies mentioned as being influenced by these factors included: stem cell technologies (the regulations regarding which were argued to be "homogenising globally over time");[86] genomics (research into which generally took place within global networks, with "pockets" of research within both high income and emerging countries);[87] GM crops;[88] and reproductive technologies (for which an international market was noted to be developing).[89]

Some respondents noted that regulatory systems were sometimes influenced by this process. Examples given include: the US intellectual property rights system which, it was argued, has been "exported" to other countries, and decisions made by the US Food and Drugs Administration (FDA) – specifically the influence on the revision of the European Novel Foods Regulation of the FDA risk assessment of animal cloning.[90]

A number of consequences related to this type of globalisation and internationalisation were noted. One respondent argued that the "ease of transit of research, researchers, and knowledge globally" has increased competition for all those involved.[91] Some respondents observed that research was now being conducted in regions and countries not traditionally associated with biotechnological research, such as the "emerging" economies,[92] and in some cases "researchers may seek out the most permissive or least regulated environment to carry out controversial research".[93] As a corollary to this, it was argued that the importance of Europe as a centre of research was diminishing.[94]

Potential benefits and drawbacks to the process of globalisation were identified by some respondents. For example, while it was argued that globalisation can help amass resources for research and development activities to an extent not otherwise possible,[95] and that as a consequence of this the speed of scientific and technological development can be increased,[96] the appropriate regulation of globalised research was seen to be almost by definition more difficult than research conducted in a single jurisdiction,[97] and might also lead to global monopolies on certain technologies.[98] One respondent viewed internationalisation of the market, in this context, as used frequently as "a spurious argument against regulation of genetic tests and to argue that the public must accept the import of GM crops into the [European Union]".[99]

The Working Party adopted the position that although science is, as an activity, generally strongly transnational, scientists themselves work in distinct locations and are subject to differing national environments which in turn have different funding climates, and funding priorities are subject to different localised public attitudes to various technologies and methods. While formal regulatory structures by necessity have a territorial basis, researchers themselves are not so limited. It was noted that this may lead to difficulties in one particular nation (or group of nations) in maintaining a policy or regulatory stance that diverges strongly from global norms.

[85] Anonymous respondent; Ines Violeta Ortega Garcìa; HeLEX Centre for Health, Law and Emerging Technologies; University of Oxford; GeneWatch UK; Anonymous respondent; PHG Foundation; Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague; Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain; Medical Ethics Alliance.
[86] Anonymous respondent.
[87] HeLEX Centre for Health, Law and Emerging Technologies; University of Oxford; PHG Foundation.
[88] Anonymous respondent.
[89] Ibid.
[90] GeneWatch UK.
[91] Dr Sara Fovargue, Law School, Lancaster University.
[92] PHG Foundation; Ines Violeta Ortega Garcìa; Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain.
[93] Medical Ethics Alliance.
[94] Hilary Sutcliffe, MATTER.
[95] Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague.
[96] LY; UK Science and Innovation Network (Canada).
[97] HeLEX Centre for Health, Law and Emerging Technologies; University of Oxford.
[98] Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague.
[99] GeneWatch UK.

Question 7: How have political traditions (such as liberal democracy) and political conditions (e.g. war) influenced the emergence of biotechnologies?

This question elicited fewer responses than previous questions but most of those who did respond felt that emerging biotechnologies were influenced by political traditions and conditions. However, one respondent argued that there has been no such influence, as "discovery is serendipitous. Politically driven initiatives lead to press conferences and publicity but seldom any breakthrough".[100]

There were sometimes fundamental differences in the manner in which respondents interpreted the meaning of the terms 'political traditions' and 'political conditions'. For example, there were differences in the understanding of the relationship between 'values' and political tradition. One respondent noted that "fundamental values" have influence on how a public views a technology;[101] another argued that political traditions have no bearing on the acceptance of a particular technology (specifically, GM crops), while also noting that attitudes such as "more ready acceptance of new technologies" and 'trust in government' played a role.[102]

Where it was specifically referenced, liberal democratic systems were generally seen as drivers of scientific and technological development, due to the greater availability of funding.[103] In one case, it was suggested that the tradition of liberal democracy encourages the development of technologies designed to enhance human welfare while the condition of war encouraged the development of technologies of human destruction.[104]

Some respondents provided examples of the influence political traditions and conditions have had on biotechnological development. One notable response suggested that orthopaedic surgery techniques were advanced in Northern Ireland during the conflict there due to the prevalence of 'knee capping', while the emphasis on autonomy by the civil rights movement provided a favourable backdrop for the development of reproductive technologies during the 1960s and 1970s.[105]

Other examples included: "the development of the contraceptive pill, abortion and IVF" (in terms of the prevailing political norms of the time;[106] see above); the promotion of biofuels in the USA in the context of energy security concerns and the associated reduction on US "dependence on foreign oil";[107] human enhancement programs funded by various elements of the USA military establishment (primarily the Defence Advanced Research Projects Agency);[108] and the differing position taken by publics in the UK and the USA with regard to stem cells.[109]

[100] Prof. Maude Phipps, Jeffrey Cheah School of Medicine & Health Sciences, Monash University.
[101] Professor Nick Pidgeon, Cardiff University.
[102] Professor Derek Burke.
[103] Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague; The Church in Wales; UK Science and Innovation Network (Canada); Anonymous respondents.
[104] Anonymous respondent.
[105] Anonymous respondent.
[106] Anonymous respondent.
[107] Anonymous respondent.
[108] Christian Medical Fellowship.
[109] Professor Nick Pidgeon, Cardiff University.

Ethical, policy and public engagement issues

Question 8: Are there ethical of 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?

Some respondents answered by listing what they thought were relevant ethical or policy issues. Others argued that there are no such common issues.[110]

One respondent noted that new technologies reflected general and contemporary societal and political concerns – such as the dominance of multi-national corporations in the high-technology sector or the meaning and importance of the concept of 'naturalness' – and this led to "unexpected resistance" to those technologies.[111] Another respondent argued that "rather than saying that there are ethical issues common to most emerging biotechnologies, I would say that there are common ethical objections to emerging biotechnologies".[112] For example, certain concerns might be held by members of the public (such as harm to human health, nature and society)[113] but, while they might be salient or important to some,[114] they are not necessarily rational.[115] Consequently, it was important for philosophers to outline a number of points regarding, for example, the inherently problematic and evolving nature of the concept of what it means to be human, or that change can itself be positive thing.[116]

Given examples of actual or perceived ethical and policy issues common, or specific to, emerging biotechnologies, included:

- consent;[117]
- control – both in terms of generalised fear of the ability to control technology[118] and the argument that emerging biotechnologies inherently *limit* control and inhibit autonomy;[119]
- environmental harms;[120]
- health and safety concerns;[121]
- human intervention in nature (/'playing God');[122]
- human nature;[123]
- justice and equity;[124]
- patenting of genes and life forms;[125]
- public understanding of science;[126]
- regulation;[127] and
- risk.[128]

The Working Party argued that there is a common ethical element to emerging biotechnologies: public interest. This arises from a number of sources, including their capacity for public benefit and harm, the public resources invested in them and the collective action such support requires, the peculiar features of the use of living systems, and their potential to transform and 'lock in' social relations and forms of discourse.

[110] Professor Bonnie Steinbock; Anonymous respondent; Research Councils UK.
[111] Professor Derek Burke.
[112] Professor Bonnie Steinbock.
[113] Dr Alan R Williamson; Professor Bonnie Steinbock.
[114] Professor Bonnie Steinbock.
[115] Dr Alan R Williamson.
[116] Professor Bonnie Steinbock.
[117] HeLEX Centre for Health, Law and Emerging Technologies; University of Oxford; Anonymous respondent; Professor Nick Pidgeon, Cardiff University.
[118] The Royal Academy of Engineering.
[119] GeneWatch UK.
[120] Anonymous respondent; Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague.
[121] The Royal Academy of Engineering; Christian Medical Fellowship.
[122] Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague; The Royal Academy of Engineering; Anonymous respondent; UK Science and Innovation Network (Canada).
[123] The Royal Academy of Engineering.
[124] The Royal Academy of Engineering; Christian Medical Fellowship.
[125] Federal Ethics Committee on Non-Human Biotechnology (ECNH); UK Science and Innovation Network (Canada); Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain; Professor Derek Burke.
[126] Anonymous respondent; Dr Sara Fovargue, Law School, Lancaster University.
[127] Professor Nick Pidgeon, Cardiff University; Christian Medical Fellowship; Powell, Buchanan, Douglas & Savulescu.
[128] Professor Nick Pidgeon, Cardiff University; Anonymous respondent; Federal Ethics Committee on Non-Human Biotechnology (ECNH); Dr Sara Fovargue, Law School, Lancaster University; Anonymous respondent.

Question 9: Do you think that some social and ethical themes are commonly overlooked in discussions about emerging biotechnologies?

Many respondents believed that a number of social and ethical themes were overlooked. Some respondents, however, felt that no themes were overlooked,[129] or that it was simply a case of these themes not being given enough importance, rather than being completely overlooked.[130] Although there was some agreement between respondents, the range of themes was notable for its breadth.

The general theme of 'justice', under a variety of guises, was raised numerous times. Some thought that there was little debate regarding how the development of – and benefits accruing from – technology, tended to be guided by and directed towards richer populations and how such decisions influenced people in countries other than those in which such decisions were made.[131] Others noted specifically issues related to fairness and intergenerational justice.[132]

In one case, two respondents' views on this topic were antithetical: one respondent argued that "most public discussions tend to focus on the risks and demand more regulation, ignoring the promise and potential benefits",[133] while another suggested that "there is a common danger that the dis-benefits of some of these biotechnologies are overlooked and/or ignored in favour of only perceived and predicted benefits."[134]

Other examples provided by respondents include:

- the necessity of differentiating between therapy and enhancement;[135]
- the status of the human embryo;[136]
- patenting;[137]
- the need for public engagement and "robust empirical work (both qualitative and quantitative) on public opinions relating to [biotechnologies];[138]
- animal welfare and how different groups construe the concept;[139]
- issues of ownership and allocation of benefits and profits relating to biotechnologies;[140]
- funding – specifically, that funding decisions are political decisions;[141]
- how biotechnological development and research is orientated – i.e. private sector with a profit motive[142] and a failure to recognise nonmonetary costs/benefits,[143] while public funding systems tend to "fund social scientists and ethicists to study the ethical and social consequences of particular commitments to science and technology but not to question why these commitments are being made in the first place."[144]
- the political and commercial motives of those opposing a technology;[145] and
- the extent to which the ostensible nature or impact of a technology generating controversy may already have manifested in other, previous, less-controversial technologies – e.g. the extent of the traits modified in plants prior to 'GM' technology.[146]

The Working Party was of the view (also espoused by GeneWatch UK in the above list) that there is a tendency to study the ethical and social consequences of particular commitments but not to question why the commitments are made. It was therefore noted explicitly in the report that such an approach (intended or otherwise) could in some circumstances inappropriately condition the development of technologies: earlier decisions frame those made at a later date; segregating different decisions into different technical 'types' to be dealt with by different expert groups can prevent broader engagement between technical domains. Because of this type of decision ordering, priorities and interests of certain technical elites may constrain the effect of other influences. Thus, reflection is restricted to the conduct and implications of a particular type of research or innovation, rather than whether the path taken is itself appropriate.

[129] Anonymous respondent; Yutaka Hishiyama.
[130] LY.
[131] RCOphth (submission from Professor Dua, President of RCOphth); Christian Medical Fellowship; Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain; UK Science and Innovation Network (Canada).
[132] Dr Sara Fovargue, Law School, Lancaster University; Anonymous respondents.
[133] Anonymous respondent.
[134] Christian Medical Fellowship.
[135] Professor Raphael Cohen-Almagor, University of Hull.
[136] Medical Ethics Alliance.
[137] Federal Ethics Committee on Non-Human Biotechnology (ECNH).
[138] Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague; PHG Foundation.
[139] ESRC Innogen Centre; RSPCA.
[140] The Royal Academy of Engineering.
[141] GeneWatch UK.
[142] Anonymous respondent.
[143] Sal Restivo & Sabrina Weiss, Rensselaer Polytechnic Institute.
[144] GeneWatch UK.
[145] Professor Vivian Moses.
[146] Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain.

Question 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?

Responses to this question broke down into a number of categories: identifying particular areas of research that have been so affected; identifying relevant processes that allow ethical, social and policy issues to feed into decision-making processes; and, arguments as to whether public engagement has a genuine impact on policy. One respondent noted that it was difficult to answer this question given "the secrecy surrounding how such decisions are made".[147]

Research into stem cells and agricultural biotechnology were mentioned by a number of respondents as having been affected by ethical, social and policy issues.[148] One respondent noted that "ethical concerns (or religious beliefs) have certainly had an impact on stem cell research in the US",[149] while others suggested that as a consequence of such concerns, there had been attempts find alternative, less ethically controversial, techniques in stem cell research (such as the use of adult, rather than embryonic, stem cells).[150] It was also argued that, given the attempt by the US state of California to provide additional funding for stem cell science in lieu of the restricted federal funding available for such research and the expected (but ultimately unrealised) "rush for research", it should be borne in mind that "there are more issues to think about for emerging technologies than a permissive regulatory environment and more funding".[151]

Some respondents saw ethical, social and policy issues as having had significant influence on the agricultural biotechnology sector. Some simply noted that there had been such an influence ("fears of GMO have had pervasive effects"[152]). One respondent believed that local or regional issues had resulted in shifts in global research patterns: French and British researchers in transgenic crops, for example, "finding their work vilified and unappreciated, either turned in other directions or left for more conducive research environments in North America and elsewhere".[153] It was also argued that the private sector agricultural biotechnology "research agenda" is orientated towards large commercial farming concerns and as such the motives are economic rather than ethical.[154] Another suggested that these issues also influenced decisions by researchers in terms of the use of particular techniques: plant biotechnology companies decided not to use 'terminator technology' or animal genes in their GM crop products due to a belief that the public would consider such practices "improper".[155]

Some respondents identified processes by which ethical, social and policy issues might formally influence some research, development and deployment: Research Councils UK noted that the BBSRC runs the Bioscience for Society Strategy Panel which is "tasked with considering the ethical and other social issues around the research that BBSRC funds"; Hilary Sutcliffe noted that the "EPSRC Nano Medicines dialogue influenced development of research".

The influence of public engagement activities on research policy decisions was called into question by some. One respondent argued that there was a "singular lack of information about how dialogue has influenced priorities"[156] and that there were "no examples where the [public engagement] commissioning body has subsequently communicated either to the participants or to the wider public the issues they have taken into consideration when making decisions and how the public engagement influenced that decision if at all";[157] another noted that there was "little evidence that public concerns have any influence on priorities for research or technological development".[158]

Part 2 of the report was dedicated to a discussion of a number of different contexts that influence the development of emerging biotechnologies. Five different contexts were identified: public perspectives, research (i.e. the role of researchers), research and innovation policy, regulation, and commercialisation.

[147] Dr Sara Fovargue, Law School, Lancaster University.
[148] David S. Jones, Massachusetts Institute of Technology, Anonymous respondents; Research Councils UK; Professor Sir David Weatherall; UK Science and Innovation Network (Canada); Yutaka Hishiyama.
[149] David S. Jones, Massachusetts Institute of Technology.
[150] Anonymous respondents.
[151] Anonymous respondent.
[152] David S. Jones, Massachusetts Institute of Technology.
[153] Professor Vivian Moses.
[154] Anonymous respondent.
[155] Anonymous respondent.
[156] Hilary Sutcliffe, MATTER.
[157] Ibid.
[158] GeneWatch UK.

Question 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?

A general point made by a number of respondents was the importance of 'weighing up' the value of an emerging biotechnology.[159] This was expressed in a variety of ways, such as harm/benefit or risk/benefit analyses. Some respondents were specifically hostile towards the use of the 'proactionary principle' mentioned in the text of consultation document,[160] or were supportive of the use of the precautionary principle.[161] No respondent that specifically responded to this question argued against the use of the precautionary principle, in the context provided, although the use of a "single, simple, all-encompassing risk-reduction principle, such as the 'precautionary principle'"[162] was cautioned against in a wider context.

Two respondents argued that there were no ethical principles to be taken into particular account when considering biotechnology and the ethical principles applied should be the same as for any other technology.[163]

Some respondents noted that there could be some difficulty in determining what principles should be taken into account on the basis that, for example, they are open to a great deal of conflict,[164] or, in some cases, it was wrong to automatically assume that a particular technology (in the specific case, synthetic biology) was inherently ethically problematic.[165] Furthermore, it was argued that "the idea that there is a set of principles that can be applied to a particular issue or problem presupposes that we understand how to describe that issue or problem" – the identification of the relevant ethical issues is, in some cases, the real ethical challenge.[166]

Few respondents ranked the principles they listed in order of importance. One response that did provide such an order of precedence was based on a religious framework; Rev. Dr Brendan McCarthy listed "affirming life, caring for the vulnerable, building community and respecting individuals" as being the ethical principles that should be taken into account, in order of precedence with "the effects of each principle 'cascading' to succeeding principles".[167] One anonymous respondent argued that prioritisation was context-specific.

Examples of the ethical principles (and concerns) that respondents felt should be taken into account include:

- animal health and welfare;[168]
- autonomy;[169]
- consent;[170]
- environmental harm;[171]
- health and safety of humans;[172]
- human dignity[173]
- human intervention in nature;[174]
- justice and equity (both inter- and intra-generational);[175]
- non-maleficence;[176]

[159] Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain; British Medical Association; Revd Dr Brendan McCarthy, National Adviser: Medical Ethics and Health and Social Care Policy, The Archbishops' Council, The Church of England; PHG Foundation.
[160] Ines Violeta Ortega Garcìa.
[161] Anonymous respondent.
[162] Powell, Buchanan, Douglas & Savulescu.
[163] Professor Vivian Moses; David Weatherall.
[164] The Royal Academy of Engineering.
[165] Powell, Buchanan, Douglas & Savulescu.
[166] Cesagen (ESRC Centre for Economic and Social Aspects of Genomics).
[167] Revd Dr Brendan McCarthy, National Adviser: Medical Ethics and Health and Social Care Policy, The Archbishops' Council, The Church of England.
[168] Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague; RSPCA.
[169] Professor Raphael Cohen-Almagor, University of Hull; Christian Medical Fellowship; Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain; Prof. Maude Phipps, Jeffrey Cheah School of Medicine & Health Sciences, Monash University.
[170] Professor Raphael Cohen-Almagor, University of Hull; Revd Dr Brendan McCarthy, National Adviser: Medical Ethics and Health and Social Care Policy, The Archbishops' Council, The Church of England; Yutaka Hishiyama; UK Science and Innovation Network (Canada).
[171] Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague; Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain.
[172] Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague; Science and Innovation Network - India; Yutaka Hishiyama; UK Science and Innovation Network (Canada).
[173] Professor Raphael Cohen-Almagor, University of Hull; Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain; British Medical Association; Christian Medical Fellowship.
[174] Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague; Ines Violeta Ortega Garcìa; The Church in Wales.
[175] Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague; Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain; British Medical Association; Christian Medical Fellowship; Dr Sara Fovargue, Law School, Lancaster University; Prof. Maude Phipps, Jeffrey Cheah School of Medicine & Health Sciences, Monash University.

- status of the human embryo;[177] and
- transparency.[178]

In the published report, the Working Party argued for a 'public ethics' of biotechnology governance (see Chapter 4 of the report for a full discussion). It was argued first that there is a distinctive public interest in biotechnology governance; second, that this interest has an ethical dimension but one that may not be unified; third, that features of the policy and innovation system often act to frame and limit the full expression of this interest and, fourth, that this interest may be restored through a particular discursive approach to policy making and governance, reintegrating biotechnology governance with the broader exercise of social interests. Three underlying public values were identified that should help guide biotechnology assessment:

- equity;
- solidarity; and
- sustainability.

Furthermore, a series of institutional and procedural virtues were described. It was noted that they should be understood as a means of influencing the business of policy making and governance, rather than the substantive content of such activity:

- openness and inclusion
- accountability
- public reasoning
- candour
- enablement
- caution.

[176] Professor Raphael Cohen-Almagor, University of Hull; Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain; Jayapal Azariah Founder President, All India Bioethics Association; Dr Sara Fovargue, Law School, Lancaster University; Prof. Maude Phipps, Jeffrey Cheah School of Medicine & Health Sciences, Monash University.
[177] Medical Ethics Alliance; The Church in Wales.
[178] Professor Raphael Cohen-Almagor, University of Hull; Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain; Hilary Sutcliffe, MATTER; UK Science and Innovation Network (Canada).

Question 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?

It was generally recognised as important by those who responded to this question that the issues of responsibility and accountability were important. However, although suggestions and examples were given as to who, and how, responsibility and accountability should be apportioned and ensured, there was also concern regarding the clarity of the concept and the general ability to implement appropriate structures to enable and enforce such apportionment.

A number of respondents noted that there was no such chain.[179] Some respondents questioned the practicalities of identifying responsibilities and establishing a chain of accountability. One respondent noted that she did not think a clear chain of accountability could be established;[180] another said that doing so would be "problematic" given that identifying responsibility and accountability is to some extent dependent on the point at which a particular level of risk is identified and that process can be itself be fraught with problems.[181] Another suggested that, in some situations at least, "there is no clear chain of accountability if a risk of adverse effect is realised" and it would be difficult to implement one "given the multitude of actors and responsibilities involved as a technology emerges".[182]

Other respondents noted inherent problems with the concept of responsibilities and chains of accountability in this context. Hilary Sutcliffe argued that the concept of 'decision making' is not clear, while another suggested that it was "unclear what the purpose of the chain of accountability is here – accountability for decision-making or for liabilities in law for adverse outcomes?"[183]

The main groups identified as having to take some responsibility were: scientists,[184] governments and their regulatory departments,[185] and individuals both singularly and as part of society.[186]

Other groups highlighted by respondents as needing to accept some responsibility in the development of an emerging biotechnology are included in the following list. Many respondents listed a number of different groups; the list should not be read as mutually exclusive.

- ethics committees;[187]
- funders;[188]
- industry;[189] and
- clinicians/the medical communities.[190]

[179] Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague; Sal Restivo & Sabrina Weiss, Rensselaer Polytechnic Institute; Dr Sara Fovargue, Law School, Lancaster University; Science and Innovation Network - India.
[180] Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain.
[181] Anonymous respondent.
[182] Research Councils UK.
[183] Anonymous respondent.
[184] Professor Raphael Cohen-Almagor, University of Hull; RCOphth (submission from Professor Dua, President of RCOphth); Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain; British Medical Association; Christian Medical Fellowship; The Church in Wales.
[185] Professor Raphael Cohen-Almagor, University of Hull; RCOphth (submission from Professor Dua, President of RCOphth); Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain; Professor Derek Burke; British Medical Association; Christian Medical Fellowship; Science and Innovation Network - India; Go Yoshizawa, University of Tokyo; Anonymous respondents; Yutaka Hishiyama.
[186] British Medical Association; Revd Dr Brendan McCarthy, National Adviser: Medical Ethics and Health and Social Care Policy, The Archbishops' Council, The Church of England; Prof. Maude Phipps, Jeffrey Cheah School of Medicine & Health Sciences, Monash University; The Church in Wales; Professor Vivian Moses.
[187] Anonymous respondent.
[188] Professor Raphael Cohen-Almagor, University of Hull; Research Councils UK ; Christian Medical Fellowship.
[189] RCOphth (submission from Professor Dua, President of RCOphth).
[190] Professor Raphael Cohen-Almagor, University of Hull; RCOphth (submission from Professor Dua, President of RCOphth); British Medical Association.

Question 13: What roles have 'risk' and 'precaution' playing in policy decisions concerning emerging biotechnologies?

The themes of 'risk' and 'precaution' were raised in relation to a number of questions by different respondents. Although respondents often disagreed on the role of 'risk' and 'precaution' in this context, it was often seen as important.[191] However, one respondent argued that although risk and precaution are important, it is not clear what role they have played in policy making because the processes behind "how decisions are reached are unclear and not always transparent"[192]

Some respondents outlined their understanding of the historical context of risk, precaution and emerging biotechnologies.[193] One argued that over approximately forty years "policy decisions in the area of the biological sciences have moved from being harm-based to being either risk or precautionary based":[194] a harm-based approach put the onus "on scientists to demonstrate the likelihood of harm"[195] of a technology before regulators become involved; risk-based approaches were designed to assess the potential risks and benefits of a particular course of action using the best scientific information available; precautionary approaches suggested "that scientific knowledge may be inadequate properly to make such risk-assessments in some cases".[196]

One respondent suggested that "the almost exclusive use of risk assessment as the regulatory hurdle for governance of new technologies, including emerging technologies, raises questions about the adequacy of scientific risk assessment for anticipating the consequences or probable consequences of those technologies",[197] specifically on the basis that polychlorinated biphenyls, thalidomide, and chlorofluorocarbons were all "subject to full regulatory risk assessment before approval for commercial use".

Three respondents in particular disagreed with the manner in which one or both of these concepts have influenced policy decisions. Drew Kershen argued that they "have played extremely negative and unjustifiable roles in policy decisions concerning agricultural biotechnology"; Derek Burke noted that the precautionary principle "is often used as an excuse for inaction"; Vivian Moses argued that "'risk' is deliberately confused with 'hazard' while precaution, instead of being seen to be a sensible approach used cautiously, is elevated to the status almost of a religion".

Some respondents noted that the roles risk and precaution have played are not necessarily the most important issues at stake. For example, the response from GeneWatch UK argued that although the role played by these concepts has been important, other issues which frame decision making processes, such as "the role of vested interests in promoting particular approaches", are often ignored.

The risks associated with inaction were also noted: the British Medical Association argued that a "balance must be found between the risks of harm from action, and the risks of harm from non-action".

The concepts of risk and precaution were major themes in the report, in terms of how they interact with the concept of uncertainty (insofar as there are some situations in which outcomes cannot be confidently characterised nor probabilities assigned, rendering risk analysis less useful) and the influence regulation can have on the development of emerging biotechnologies (i.e. how regulatory interpretations of precaution might be reframed to more appropriately reflect a 'proper' understanding of precautionary approaches.)

[191] Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague; Drew L Kershen, Professor of Law (U.S.A.); Nishat Hyder, on behalf of iSEI and CSEP, University of Manchester; Professor Nick Pidgeon, Cardiff University; GeneWatch UK; Cesagen (ESRC Centre for Economic and Social Aspects of Genomics); British Medical Association; Professor Sir David Weatherall; UK Science and Innovation Network (Canada); Yutaka Hishiyama; Anonymous respondent.
[192] Dr Sara Fovargue, Law School, Lancaster University.
[193] Revd Dr Brendan McCarthy, National Adviser: Medical Ethics and Health and Social Care Policy, The Archbishops' Council, The Church of England; Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain.
[194] Revd Dr Brendan McCarthy, National Adviser: Medical Ethics and Health and Social Care Policy, The Archbishops' Council, The Church of England.
[195] Revd Dr Brendan McCarthy, National Adviser: Medical Ethics and Health and Social Care Policy, The Archbishops' Council, The Church of England.
[196] Revd Dr Brendan McCarthy, National Adviser: Medical Ethics and Health and Social Care Policy, The Archbishops' Council, The Church of England.
[197] Cesagen (ESRC Centre for Economic and Social Aspects of Genomics).

Question 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?

Many respondents thought that it would be difficult, or impossible, to regulate emerging biotechnologies using a single framework.[198]

A common position was that the very nature of 'emerging biotechnologies' prevented, or made difficult, such an approach – it was felt that the term encapsulates a number of technologies with different implications, rendering a single framework less effective as a regulatory tool than sector-specific methods.[199] One respondent argued that one should beware the assumption that "all emerging biotechnologies raise the same theoretical and practical issues" and avoid "overly simplistic and ill-defined terms of opprobrium, such as 'unnatural,' 'commodification' and playing God".[200]

Some respondents felt also that a single approach would not only be impossible, but also undesirable or unnecessary:[201] it was noted that such an approach would "reduce [regulation] to the exchange of dogmatic statements for and against".[202]

While the main thrust of the responses was that a single framework would be difficult or impossible to implement, some stated that a single framework would be desirable.[203] Others noted that a dual-approach was desirable and in some cases possible.[204] One suggestion made by a number of respondents was to have some kind of framework or body with overall responsibility for emerging biotechnologies, within which different departments would be responsible for discrete technological areas.[205] In the final report, the Working Party recommended that consideration should be given to bringing Government research policy and funding bodies under a senior minister, free from departmental responsibilities to ensure that research properly reflects all the objectives of Government, rather than those of a particular department.

Two respondents specifically mentioned the UK Human Fertilisation and Embryology Authority (HFEA) with respect to regulatory frameworks. Bonnie Steinbock argued that "it is possible that there could be a single agency in the UK, analogous to the HFEA, which served as an umbrella for differing technologies" provided that the establishment of such a body did not lead to an approach that treated all emerging biotechnologies as raising the same theoretical and practical issues. Another respondent noted that the HFEA was "seen as a model of governance worldwide" and suggested that the process leading up to the creation of the HFEA ("lengthy, extensive debate and consultation with all interested parties including the general public") should be used in the development of a regulatory framework for emerging biotechnologies.[206]

Some responses sounded notes of caution not specifically about the practicality or desirability of implementing a single regulatory framework, but about the manner in which the issue is considered more generally. For example, it was argued that regulatory systems can have a "profound impact not only on innovation trajectories, but also on public acceptance and social uses of technologies"[207] and an often overlooked issue was "that existing regulatory regimes have their own particular (peculiar) history, concepts, institutions, overarching objectives and mores, and mechanisms"[208] which must be accounted for when considering future regulatory systems for emerging biotechnologies.

It was the position of the Working Party that it was very rare for there to be a single 'right' regulatory solution to any particular 'problem'. Rather, the most appropriate approach is to ensure that any decisions in opening up or closing down ranges of options are subject to suitable ethical reflection. It was argued that this is especially the case in those situations characterised by conditions of ambiguity and uncertainty, such as regulatory decisions concerning emerging biotechnologies.

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[198] Anonymous respondent; Professor Nick Pidgeon, Cardiff University; Dr Sara Fovargue, Law School, Lancaster University; Jayapal Azariah Founder President, All India Bioethics Association; Hilary Sutcliffe, MATTER; Anonymous respondents; Dr Christopher French; David S. Jones, Massachusetts Institute of Technology; RSPCA; Yutaka Hishiyama; The Church in Wales; Dr Sara Fovargue, Law School, Lancaster University.

[199] Professor Nick Pidgeon, Cardiff University; Dr Sara Fovargue, Law School, Lancaster University; Revd Dr Brendan McCarthy, National Adviser: Medical Ethics and Health and Social Care Policy, The Archbishops' Council, The Church of England; Dr Christopher French; David S. Jones, Massachusetts Institute of Technology; RSPCA; Yutaka Hishiyama; Dr Sara Fovargue, Law School, Lancaster University.

[200] Professor Bonnie Steinbock.

[201] Professor Derek Burke; Anonymous respondent.

[202] Professor Derek Burke.

[203] Anonymous respondents; Sal Restivo & Sabrina Weiss, Rensselaer Polytechnic Institute; Science and Innovation Network - India; Go Yoshizawa, University of Tokyo.

[204] RCOphth (submission from Professor Dua, President of RCOphth); Anonymous respondent; Dr Sara Fovargue, Law School, Lancaster University; Ines Violeta Ortega Garcìa; Hilary Sutcliffe MATTER; GeneWatch UK; Christian Medical Fellowship.

[205] RCOphth (submission from Professor Dua, President of RCOphth); Anonymous respondent; Jayapal Azariah Founder President, All India Bioethics Association; Ines Violeta Ortega Garcìa; GeneWatch UK; Professor Sir David Weatherall.

[206] Nishat Hyder, on behalf of iSEI and CSEP, University of Manchester.

[207] ESRC Innogen Centre.

[208] ESRC Innogen Centre.

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

This question elicited a considerable number of responses and provoked notably divided reactions. Responses can be broadly divided into those that take the position that it is important that public opinion plays a role in the development of policy around emerging biotechnologies, and those that accept that while this might be the case, there are important problems to consider. Rejection of the import of public opinion was rare, although one respondent argued that where a technology was restricted to use only in laboratories, public opinion was not important.[209]

It was argued by some of those who believed that public opinion has a role to play that it was "crucial",[210] "fundamental",[211] "a must",[212] "very important"[213] and "essential for policy development that will carry public support".[214] There were a number of other respondents who expressed similar sentiments to the effect that public opinion should play an important role.[215] One respondent argued that public opinion was a counterbalance to corporate profits: "public opinion should play a much larger role than it does now (that is, if one values democratic principles more than maximising corporate profit)".[216] Some respondents noted that public opinion already played a role.[217]

A number of problems relating to the use of public opinion in policy-making were identified. The main problem respondents highlighted in this context was the manner in which public opinion should inform policy: decisively, or merely as one part of the policy making process? A number felt that it should be taken into account, but only into account as one element of the process;[218] public opinion was considered "fickle"[219] by one respondent, argued not to be a "panacea"[220] by another and that "in the last analysis, [policy] must be determined by accurate scientific information and sound philosophical arguments"[221]

Another theme that emerged in this context was the nature of public 'understanding': public opinion could be misinformed.[222] One respondent noted that "more often than not the publics we engaged with had little experience, awareness and knowledge of these new scientific developments; and to be frank, were often uninterested in them"[223] while another noted that "the public are constantly being bombarded with half-truths."[224] Another argued that "for democracy to work properly one needs an educated electorate" and it was "not easy to see how to fairly inform the public".[225] Alan Williamson suggested that "if we are to have any meaningful democratic involvement in decision making concerning new biotechnologies then we need a scientifically educated public";[226] he went on to argue that the same requirement applied also to policy makers.

The Working Party concluded that there was no 'royal road' to effective public engagement. Rather, it was noted in the report that careful and critical attention must be given to the alignment of method with the underlying rationale for engagement, and the aims and expectations of engagement should be understood in advance; outcomes should be reported in a properly contextualised and conditional way, rather than as simple prescriptive advice.

[209] Yutaka Hishiyama.
[210] Professor Raphael Cohen-Almagor, University of Hull.
[211] RSPCA.
[212] Jayapal Azariah Founder President, All India Bioethics Association.
[213] Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain.
[214] British Science Association.
[215] Professor Nick Pidgeon, Cardiff University; Nowgen; Christian Medical Fellowship; Revd Dr Brendan McCarthy, National Adviser: Medical Ethics and Health and Social Care Policy, The Archbishops' Council, The Church of England; Anonymous respondents; Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague; GeneWatch UK; Simone Penasa; Dr Sara Fovargue, Law School, Lancaster University; Anonymous respondent.
[216] Anonymous respondent.
[217] Anonymous respondent; Dr Christopher French.
[218] Professor Bonnie Steinbock; Research Councils UK ; Wellcome Trust; PHG Foundation; The Royal Academy of Engineering; Dr Sara Fovargue, Law School, Lancaster University.
[219] Professor Derek Burke.
[220] Hilary Sutcliffe, MATTER.
[221] Professor Bonnie Steinbock.
[222] Anonymous respondent; Professor Vivian Moses; UK Science and Innovation Network (Canada).
[223] ESRC Innogen Centre.
[224] Professor Sir David Weatherall.
[225] Professor Derek Burke.
[226] Dr Alan R Williamson.

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

Some respondents provided comment on the 'background' to effective public engagement, rather than specific and direct suggestions about which forms of public engagement are most valuable with regard to emerging biotechnologies.

For example, the issue of whether the public was 'informed' enough to engage sufficiently was brought up in a similar manner to those responses to Question 15. One respondent noted that "first of all, the public needs to be correctly informed";[227] another that "knowledge and correct information is the key to successful public engagement".[228] The PHG Foundation highlighted that although there was a difficulty in "ensuring that publics are sufficiently educated",[229] it was important to understand that "merely to regard these educational needs in terms of a 'deficit' that needs to be filled should be regarded as paternalistic and outdated".[230] Professor Sir David Weatherall noted that there is a lack of communication between scientists and the public in the UK, arguing that the only direct means of communication in this context were science festivals.

The nature, limitations and context of public engagement activities were the subject of some comment. For example, ESRC Innogen noted that "levels of public involvement may vary and involvement does not necessarily mean empowerment nor inclusion". Hilary Sutcliffe raised the question of whether public engagement could be considered a good use of time by a member of the public; she argued that the public in general is less interested in engagement and more interested in transparent decision making processes, noting that "there are things that the public themselves want to know and engage about, but much that they expect and hope that professional stakeholders, such as NGOs, consumer groups and others do on their behalf". One anonymous respondent argued that the purpose behind public engagement activities must be clear, noting that "The [Nuffield Council on Bioethics] consultation seemed to indicate that public engagement is aimed at fostering understanding, trust and acceptance" and that "if policy makers do seek to engage with the public then they must do so in a meaningful way, without presupposing the outcome". The response from GeneWatch UK seemed to concur with this position: "activities to date, whilst often leading to interesting and valuable discussions, have usually been set up with a view to maintaining the existing system of decision-making".

A number of comments were made on suitable approaches to, and methods for, the evaluation of public engagement; evaluation was seen as challenging.[231] One respondent argued that the critical factor in public engagement is making it "effective".[232] Research Councils UK noted that evaluation of public engagement activities is "key" and must be independent. It was argued that proper evaluation could only take place if clear objectives had been set.[233] Hilary Sutcliffe suggested that 'internal reflection' by organisations on the outcome of the public engagement was "more important than the public engagement itself".

There were some suggestions regarding how particular public engagement methods and activities might be used within the context of emerging biotechnologies. These included ensuring activities are tailored to the specific purposes of the process;[234] art;[235] holding public conferences, hearings and workshops;[236] publishing articles in the press to raise awareness;[237] holding focus groups and citizen's juries;[238] and, the use of mass media.[239]

[227] Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain.
[228] RCOphth (submission from Professor Dua, President of RCOphth).
[229] PHG Foundation.
[230] PHG Foundation.
[231] Nowgen; Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain.
[232] Dr Otakar Fojt, Science and Innovation Network, British Embassy Prague.
[233] Nowgen.
[234] Nowgen.
[235] Go Yoshizawa, University of Tokyo.
[236] Anonymous respondents; Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain; Dr Sara Fovargue, Law School, Lancaster University; Yutaka Hishiyama.
[237] Anonymous respondent; Mertxe de Renobales Scheifler, University of the Basque Country / EHU, Spain.
[238] Nowgen.
[239] Science and Innovation Network – India.

Question 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?

A number of views were expressed by those who believed there is something unique about emerging biotechnologies:

- that democratic representatives often have little or no familiarity with scientific issues;[240]
- the direct effect on the the individual or his/her children and, as a consequence, the greater level of public interest in emerging biotechnologies;[241]
- that the emergent and 'bio' aspects of emerging biotechnologies may separate them from other policy making areas" and that "public perceptions of 'bio' can draw on the concepts of naturalness and nature which are often portrayed as being in conflict with biotechnological development";[242]
- that emerging biotechnologies "have the potential to challenge existing socially and legally-accepted definitions of fundamental concepts – life, death, human, person, free, owned, natural, artificial";[243]
- that emerging biotechnologies may *inherently* present greater risks than other technologies;[244] and
- the impact such technologies have on the right to property of the body and informed consent;[245]
- the implications for human health;[246]
- public unfamiliarity.[247]

Some of those who believed that emerging biotechnologies showed no such unique properties in this context provided the following justifications:

- two respondents argued that emerging biotechnologies and emerging technologies in general should be treated in the same way and be subject to similar public engagement exercises.[248]
- that "each type of emerging technology might have a particular package of issues associated with it" and therefore a single mechanism for public engagement might not be justified;[249]
- the Royal Academy of Engineering argued that not only did all "special kinds" of public engagement go beyond the usual democratic channels, but there was nothing "unique to emerging biotechnologies that demands these public engagement activities"; and
- one respondent noted that a common argument for why emerging biotechnologies might be unique (bodily intervention, health, nature etc.) also applies to many other policy areas (military, industry, tax) – it was better therefore to give "careful consideration of all of them".[250]

The British Science Association considered it "unclear what is meant…by 'outside the normal democratic channels'." They argued that open public discourse, and public engagement in its various forms, already forms part of the normal democratic channels "and that public fears regarding biotechnologies do not necessarily require special kinds of public engagement, but may suggest a need for "more attention to appropriate public engagement" generally.

The Working Party took the position that effective public engagement is necessary in the context of biotechnologies (not only emerging biotechnologies) but that such technologies are not necessarily unique in this when compared to other areas of policy making which concern public monies, especially where the subject is opaque and technocratic. Other, more specific arguments concerned the aforementioned public interest in biotechnologies, the way (especially in the UK) research policy is to a significant extent determined by bodies such as the Research Councils, which are more remote from Parliamentary accountability than Government departments and, finally, the way discussions of science policy in Parliament are often couched in terms of 'sound science', meaning that debates typically fail to consider the potentiality of social choice among alternative technological trajectories.

[240] Professor Sir David Weatherall.
[241] RCOphth (submission from Professor Dua, President of RCOphth).
[242] Research Councils UK.
[243] Sal Restivo & Sabrina Weiss, Rensselaer Polytechnic Institute.
[244] Dr Sara Fovargue, Law School, Lancaster University.
[245] Professor Raphael Cohen-Almagor, University of Hull.
[246] Nowgen; Anonymous respondent10.
[247] Yutaka Hishiyama.
[248] Anonymous respondents.
[249] PHG Foundation.
[250] David S. Jones, Massachusetts Institute of Technology.