Nuffield Council on Bioethics:
Emerging Technologies Consultation Paper
ESRC Innogen Centre Submission
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This is a response from the Economic and Social Research Council (ESRC) Centre for Social and Economic Research on Innovation in Genomics (Innogen), based at the University of Edinburgh and the Open University. Innogen researchers study innovation in the life sciences and address the social impact of innovation on global health, agri-food, the environment and the economy.

The life sciences have the potential to transform health care and food production systems in developed and developing countries and to provide one of the main platforms of economic growth and global competitiveness in the 21st century. Rapid developments in life sciences challenge our existing regulatory systems and raise new ethical and social issues. Innogen's research aims to provide a sound base for decision-making in science, industry, policy and public arenas related to innovation in life sciences.

For over twenty years staff at Innogen have researched issues of regulation, innovation and engagement in the life sciences and in other sciences and technologies of information, communication, energy and environment. The researchers working at Innogen include social scientists, economists and lawyers who engage with a wide range of stakeholders - nationally and internationally - including scientists, industry and private interest groups, policymakers and regulators, and citizens and public interest groups.

Summary of response

This response draws on Innogen's research and expertise in social, economic and legal issues around genomics and public health. We have answered only those questions where we have specific data/expertise to make an informed and meaningful contribution to the consultation.

Our evidence and conclusions can be summarised as follows:

- Emerging technologies are likely to raise issues specific to the application itself.
- Cloned animals offer an example where social, cultural and geographic factors have influenced their development.

- We highlight the importance of all potential 'convergent technologies' not just 'biotechnologies', for example, implantable devices.

- While animal welfare is usually considered as part of ethical considerations, this is absent in the list generated for responses.

- Existing regulatory regimes have their own 'regulatory heritage'. There is a need to work towards 'smart regulation', which is to say regulation that is timely, democratic, consistent, coherent, practical and stable, but also flexible or amendable.

- Given the power of emerging biotechnologies with respect to human wellbeing, human identity and environmental stability, it is important that publics are consulted early and often using a range of discursive methodologies.

- The position of social scientists involved in these 'engagements' remains rather unclear and the issue of 'framing' warrants further attention.
- Levels of public involvement may vary and involvement does not necessarily mean empowerment nor inclusion.

- Public engagement is laudable as an ideology but difficult as a methodology.

- Scientists, as well as other groups of stakeholders, hold a range of views and this should be reflected in evidence-informed policy rather than relying on a few scientists who have achieved prominence. They should also come from a range of disciplines and sectors (e.g., research and clinical scientists, molecular biologists and ecologists).

- Public engagement should take into account the regulatory constraints that exist within the area. Many engagement exercises appear to ignore the fact that regulation already exists for many technologies.

Consultation questions

Q1. How would you define an 'emerging technology' and an 'emerging biotechnology'? How have these terms been used by others?

The terms 'emerging technology' and 'emerging biotechnology' tell us very little. The term 'new and emerging science and technology' (NEST) appears more and more in the literature, but, again, this term is not well defined; for example, what counts as 'new'? What criteria do we apply and is this criteria commonly understood across practice boundaries? How do we account for new uses of old technologies? Xenotransplantation, we might argue, is a negative case example of NEST; it is now neither new nor emerging and its development has repeatedly stalled (Haddow et al., 2011)[1]. Furthermore, it is interesting that technologies such as DNA databanks, stem cells and ARTs (Assisted Reproductive Technologies) have not been included in the consultation as these appear to fulfil the criteria offered.

A further caution is warranted that relates to the fact that, although a basic understanding of NEST is within our reach, their consequences cannot be fully predicted as their trajectories are likely to be uneven, complex and non-linear (Williams 2006)[2]. Furthermore, no consensus on their social uses or implications can be expected; positions formed as a result of foresighting activities tend to be polemically utopian or dystopian in nature, but even when they are more balanced and nuanced, they are likely to get many things wrong. That is not to say foresighting should not be done; it means we have to be careful how we do it and clear about what we might expect from it.

Q2. Do you think that there are features that are essential or common to emerging biotechnologies? (If so, please indicate what you think these are.)

Emerging 'biotechnologies' are likely to raise issues that are specific to particular technologies and particular applications rather than to each emerging biotechnology itself. For example, applications of nanotechnologies to food are likely to raise different issues than applications of nanotechnologies to medicine. Citizens and publics consistently argue for technologies to be developed out of social need rather than purely for profit (an element of profit is accepted), yet it is sometimes difficult to discern when this is the case.

Acceptability of developments may also be contingent on a range of conditions being met, such as the technology being applied in just ways and not favouring particular groups. If the cases of cloned and GM animals, GM crops and applications of stem cells are considered together, a common feature of these biotechnologies may include an underplay of the practical realities of bringing these products to market, due to the strong role of research scientists in developing visions for these technological developments in the future; this may engender resistance from social groups that feel scientists have too much power. Additionally, in practice, lessons have been learned from the decisions made about GM crops which have been taken into account in discussions concerning cloned and GM animals and stem cells.

However, while GM crops and GM animals may be discussed in public in similar ways, they encompass rather different technological possibilities and limitations that are embedded in very different industry structures (Bruce, 2007)[3]. Again, evidence about the acceptability of genetic modification suggests that this depends on the species being modified and the specific application. Thus, applications to humans appear to be the most controversial, followed by animals, plants and micro-organisms; medical applications are more acceptable than applications to food (e.g. Gaskell et al. 2007)[4].

A common argument in support of the development of technologies is one of increasing national wealth and job creation. While this may be the case with stem cell research, the same argument does not stand for cloned and GM animals; rather, an argument more commonly applied to the latter technologies focuses on the need to ensure a level playing field for EU industry and continuing competitiveness.

Hence generally, these seem to be areas of 'golem science'; science which has not yet gained scientific knowledge consensus (Collins and Evans, 2002)[5] nor public support for early intervention, as the possible risks of a technology are still to crystallise. However, later technologies may see the governance and vested interests already locked in.

Q3. What currently emerging biotechnologies do you consider have the most important implications ethically, socially, legally?

This is a difficult question as it requires familiarity with all manner of technologies considered in a dynamic and competitive setting and in a comparative way. Further, as noted above, the trajectory of technologies are unlikely to be linear. Why some technologies appear to generate controversy and not others has been much debated and is addressed by a considerable body of research beginning with Starr (1969)[6].

That said, some of the most dynamic fields at present are those that merge technologies from very different fields, not all of them purely 'bio'. For example, nanotechnologies, information technologies and medical diagnostics, combined with progress in medical knowledge and technologies generally, are quickly leading toward very sophisticated implantable devices. These technologies will become more 'bio' as advances are made in cellular research and bio-nano research and therefore the implications of their uses will require important ethical, social and legal consideration.

In any event, we would suggest that the solutions (legal, policy or otherwise) to emerging ethical, legal or social issues must be much more imaginative than has been the case in the past. In particular, while we must be very cautious about permitting NEST to erode important (human) rights, the re-emphasis of consent as the sole or primary lynchpin of ethical governance strategies is not warranted. Rather, we must recall the purposes of governance activities: to encourage knowledge generation, to facilitate the development of socially useful applications/technologies and to justify and promote public trust. Governance

activities are to do this while simultaneously limiting the risks to which individuals, society, and the environment are exposed, within the context of a particular economic paradigm. We must fashion our instruments and institutions to consider and address these matters as consent cannot do all of this work.

Q4. Are there examples where social, cultural and geographical factors have influenced the development of emerging biotechnologies?

Cloned animals offer an example where social, cultural and geographic factors have influenced their development. In Europe, three countries have specific legislation relating to animal cloning. In the Netherlands, the Animal Health and Welfare Act of 1992 prohibits applications of biotechnology to animals without a special licence. The criterion for being given a licence includes that the goal of the research is of substantial importance to society, there are no alternatives and the benefits outweigh the risks to health, welfare and the integrity of the animal. This requirement for a special licence is ostensibly the reason why the Dutch company Pharming (developing pharmaceutical products from GM animals) relocated its animal facilities to Belgium and the US, although this is contested. Denmark has enacted legislation to ban the use of animal cloning and genetic modification for agriculture except for experimental purposes citing concerns about animal welfare and animal integrity. In Norway animal cloning has been banned; concerns about enabling human cloning appear to be implicated in that decision. There are many other countries in Europe and elsewhere where such practices are allowed.

Q9. Do you think that some social and ethical themes are commonly overlooked in discussions about emerging biotechnologies? If so, what are they?

While animal welfare is usually considered as part of ethical considerations, this is absent from the Nuffield Council list. Animal welfare is a difficult concept that can encompass different things for different people. Fraser (2003)[7] identifies three main ways in which animal welfare scientists have understood welfare. These different approaches are not just academic distinctions as they may have real regulatory consequences, described by the same author. The desire for ‘good animal welfare’ may be understood as avoiding pain to the animal, or allowing it to behave in natural ways or to encompass some concept of animal integrity.

Lassen et al (2006)[8] describe how lay understandings of welfare may also differ from that of specialists, noting how dirt on pigs was seen as a positive indicator of welfare by publics they engaged (as indicating natural conditions). This is not a criterion likely to be used by specialists in animal welfare. It is therefore important to be clear as to what is meant by ‘animal welfare’ in a particular circumstance.

Q13. What roles have ‘risk’ and ‘precaution’ played in policy decisions concerning emerging biotechnologies?

We comment on the legislation being considered in the EU regarding food from cloned animals. There is little evidence that the EU public want this technology and EU industry seems to be more concerned with ensuring a level playing field (or European competitiveness) should the technology be adopted elsewhere, rather than advocating cloning as a technology per se. There is little evidence that the products from progeny of cloned animals are unsafe to eat (although this is a concern with publics). The issues appear to be as much associated with negative connotations associated with cloning as well as animal welfare concerns. Arguments against farm animal cloning were made even by those members of the European Parliament who would normally seem to advocate

biotechnological developments.

The regulation therefore appears to be less a case of regulating a hazardous technology and more one of causing and responding to nebulous anxiety on a variety of different levels. An outright ban on cloning might restrict applications that were not at the forefront of policymakers thinking at the time, for example, the potential availability of stored cells from rare and endangered breeds of livestock in a biobank to 'recreate' animals using cloning technology in case of a sudden disease outbreak or natural disasters that would otherwise decimate irreplaceable genetic resources.

Q14. To what extent is it possible or desirable to regulate emerging biotechnologies via a single framework as opposed to individually or in small clusters?

The regulatory regime can have a profound impact not only on innovation trajectories, but also on public acceptance and social uses of technologies. In a study of GM crops, pharmaco-genetics and stem cells, Tait (2007)[9] identifies the simultaneous impact of innovative technologies on regulatory systems, markets and sectoral innovation systems. Therefore, while it may seem desirable to regulate on the basis of small clusters, the implications of the regulation need to be carefully thought through. An important but often overlooked issue is that existing regulatory regimes have their own particular (peculiar) history, concepts, institutions, overarching objectives and mores, and mechanisms (i.e. they have their own 'heritage' which may or may not suit the NEST in question) (Stokes, 2011)[10]. These must be accounted for when deciding how to deal with NEST (or where to put them from a regulatory perspective).

Most important is to identify a 'good governance framework' (Laurie, 2011)[11] and work toward 'smart regulation', which is to say regulation that is timely, democratic, consistent, coherent, practical and stable, but also flexible or amendable. Ultimately, it is not desirable to regulate NEST through further add-ons to the existing complex and increasingly fragmented regulatory environment in the science and technology setting. The nature of the technology, its processes and objectives, and ultimate markets are all important factors in determining how it is regulated. For example, stem cell research for regenerative medicine is subject to weighty regulations, however stem cell research can be used for cosmetic purposes without legislation. Similarly, GM pets (such as GM tropical fish in the US) are unregulated, however, the use of GM animals in the livestock industry is beset by heavy regulation.

Q15. What role should public opinion play in the development of policy around emerging biotechnologies?

Given the complexities and intricacies of NEST, opinion as collated and measured by opinion polls are likely to give results that have not allowed the respondents' the time, information or opportunity to deliberate on the issues (assuming that they so wish to). Public engagement (PE) differs from other forms of consultation or research insofar as it occurs (or should occur) in a timely fashion prior to the technology becoming 'locked in'. Engagement occurs 'upstream' - 'upstream' is not just about early or timely research, but also about having the potential for early and ongoing engagement about fundamental questions that have the opportunity to influence processes and outcomes (Wilsdon and Willis, 2004[12], Harmon, 2006[13]). In our recent experience we have found that that upstream engagement needs to be nurtured because open-ended dialogue does not spontaneously arise. Respondents' degree of engagement at such an early stage of development and with little prior information can be limiting (Haddow, Cunningham-Burley, et al, 2008)[14].

Given the power of emerging biotechnologies with respect to human wellbeing, human identity and environmental impact, it is essential that publics are consulted early and often

using a range of discursive methodologies. In short, participative engagement between publics, policymakers, interested stakeholders and others must be systematised. However, while public opinion is important, it is little use to simply ask people what they think of NEST. Engagement will be more fruitful (and useful) if it focuses on exploring cherished values held by people and how NEST interacts with those values, the desires for the social aims of NEST, and how people address difficult trade-offs between competing values held by individuals; the potential benefits and safety of a technology and its potential risks; and the likelihood of the risks and benefits and to whom they accrue. Engagement must focus on articulating and then fashioning means to secure the futures that publics desire.

This question might also consider the role of social scientists?

Consulting and engaging with sectors of the UK population on the development of new and emerging science and technologies, such as GM crops, stem cell technology and DNA databases, is considered to be of fundamental importance by some politicians, funding bodies, scientific organisations and social scientists. Social scientists have become involved with these PE activities – studying their operation and impacts and often supporting their activities. However the position of social scientists involved in these 'engagements' remains rather unclear.

In recent years, the social scientists at Innogen have become involved in PE activities with a number of groups (public, regulatory, academic, etc.) on various new scientific and medical technologies. Again and again, we have come across the problem of how to present complex technical, legal, ethical and social issues about these technologies to our participants. There is, after all, a fundamental difference between asking people for their views on a particular topic based on their experience of it and asking people for their views based on little experience or knowledge. 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 (Haddow, Cunningham-Burley, et al, 2011)[15].

To reiterate, the problem is one of engaging with lay publics or with specialist communities (politicians, managers, specialists, etc.) on areas outside their specialism. This is why the issue of 'framing' comes to the fore. There has been much criticism from Science and Technology Studies colleagues about the disposition of scientists to persuade publics that the science they are conducting is good and fair by framing the issues in a particular way. A much overlooked issue in these interactions is the problem of 'framing' by the social scientists themselves. The role of 'framing' in social interactions can be traced back to the classic work of Goffman who suggested that, 'definitions of a situation are built up in accordance with principals of organization which govern events, at least social ones, and our subjective involvement in them; frame is the word I use to refer to such of these basic elements' (Goffman, 1974)[16]. Gitlin provides a convenient accessible definition: 'Frames are principles of selection, emphasis and presentation composed of little tacit theories about what exists, what happens and what matters' (Gitlin, 1980)[17]. It is this question of 'what matters' that has emerged in some of our latest research.

As social scientists, seeking to elicit the views of diverse constituencies in the course of fieldwork or PE activities, we may need to convey something about complex technical fields and associated social issues and policy debate. Time constraints, let alone the limits to our technical understanding, mean we can only provide a condensed and simplified account of these complex issues. Such simplification brings a risk of misinterpretation by giving some aspects greater emphasis than others. So no longer is it only about making sure that we do not ask leading questions, but it is the ability to present debates, issues, etc. that are provocative but reasonable; that stimulate debate but do not antagonise; that do not capture our respondents by our own analytical commitments and vested (critical) interests.

Social scientists involved in PE activities around particular scientific or technological developments as ‘critical friends’ of scientists are faced with additional questions such as, ‘How do we present information that does not alienate and antagonise scientific colleagues through inaccuracies, ignorance or unintended bias, yet allows the social scientist to present contested debates?’. We are simultaneously faced with a problem that the ‘picture we present’ of such advances are to be inclusive, do not lead to power-differentials, do not ‘capture’ the audience by our (conscious or unconscious) vested interests, do not lead to premature consensus and presents the information in a fair and unbiased way. Some commentators have tended to discuss the issue of framing as a conscious strategy to lead (or mislead) those being engaged with towards a particular view (McCombs and Estrada 1997)[18].

Q16. What public engagement activities are, or are not, particularly valuable with respect to emerging biotechnologies? How should we evaluate public engagement activities?

The ‘valuable’ in this question might be clarified perhaps in relation to who and for what purpose? Levels of public involvement may vary and involvement does not necessarily mean empowerment nor inclusion. PE is laudable as an ideology but difficult as a methodology. It raises questions such as, ‘How to open up a space for critical dialogue and enquiry in public engagement activities?’ and ‘How to link this to decision making, at what stage and about what issues?‘.

In response to the first of the two consultation questions, we advocate the following ‘rules of engagement’ for PE activities:

- Engagement is not a panacea for resolving issues around contested technologies. Engagement will not necessarily avoid conflict or avoid making mistakes with technological developments. However, as a manifestation of democracy (as a value) and as a means of arriving at more inclusive and creative governance solutions, it is important.

- Tait (2009)[19] and Harmon (2010)[20], (2011)[21] advocate the development of approaches that encourage equitable dialogue across all societal groups, scientists, industry, regulators, NGOs and citizens. We should develop 'rules for engagement' that set standards for the quality and breadth of evidence that is brought to the discussions, and that encourage a willingness to listen to and accommodate, where possible, the views of others. We should also consider carefully the circumstances in which it might be necessary or valid to allow the values and interests of one group to restrict the freedom of choice of others. This is also reflective of calls to open up informed bioethical debates to much more interdisciplinary groups (O’Malley et al. 2007)[22].

- It should be acceptable to make a case about the adoption of a technology based on values where these are salient. It is suggested that with respect to GM crops, all arguments had to be expressed in terms of risks because the issue was seen as one of risk regulation (Tait, 2001)[23]. This meant that people who wanted to argue based on values or ethics or alternative conceptions of a desirable future had to do so based on risk. The risk regulatory regime was not designed to cope with such a range of arguments.

- An opportunity may need to be created to specifically allow engagement with any values-dimension, and also to manage expectations, such as overtly positive evaluations of the prospects of developments. Given the likely political nature of decisions, there will need to be careful management of such spaces, but also potentially ongoing engagement particularly where circumstances (scientific

developments and social developments) are rapidly changing.

- Recognise that scientists, as well as other groups of stakeholders, hold a range of views. This range should be reflected in evidence-informed policy rather than relying on a few scientists who have achieved prominence in their field. In other words, engage with a range of scientists that cover more than the immediate research area and who represent different institutions and possibly different levels in the hierarchy. For example, evaluation of the prospects from regenerative medicine have been different by research scientists and by medical researchers involved in clinical practice. Engaging a wider dialogue across a range of natural and social sciences and professionals will bring in a range of salient expertise.

- Public engagement should take into account the regulatory constraints that exist within the area. Many engagement exercises appear to ignore the fact that regulation already exists for many technologies.

- Debates may quickly become framed in particular ways that then tend to cause future argumentation to be expressed in similar ways. It is therefore important not to ignore any 'hidden issues' that may have low profile but may nevertheless be important.

Q17. 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 biotechnologies have come to signify much more than just the physical manipulation of (often genetic) material - they are raising wider questions that may challenge some strongly held views, such as corporate control over the basic elements of human survival and appropriate ways of treating the natural world. There is evidence that while seeking more scientific evidence may improve the decision-base or serve as a delaying tactic for making controversial decisions, more scientific evidence is unlikely to resolve disputes where there is a strong value basis (e.g. Fisher & Ury 1987[24], Jasanoff 1990[25], Nelkin 1992[26], Schön & Rein 1994[27], Pielke 2007[28]). This type of decision may therefore require special kinds of public engagement outside the normal democratic channels[29].

Overall one might consider the following questions when engaging the public on issues of biotechnology:

- What is the motivation for undertaking the exercise?

- What enthusiasm is there for dialogue?

- For how long will the engagement be sustained? (It can take a long time.)

- Will aims and expectations match i.e. between funders, organisations, social scientists, public(s)?

- The How & 5 Ws – who, what, when, where and why?

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