

This response was submitted to the consultation held by the Nuffield Council on Bioethics on Emerging biotechnologies between April 2011 and June 2011. The views expressed are solely those of the respondent(s) and not those of the Council.

## **Response to the Nuffield Council on Bioethics Consultation Paper on Emerging Biotechnologies**

From

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On behalf of

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<sup>1</sup> SCuLE is an interdisciplinary research group at Exeter University focusing on Intellectual Property Law, Human Rights, Bioethics, and Information Law. We provide leading contributions to the vibrant theoretical and practical discourse on matters of policy, governance, regulation and culture relating to these fields. More information about the group may be found at <http://socialsciences.exeter.ac.uk/law/research/scule/>.

<sup>2</sup> Z. Bauman. 2007. *Liquid Times. Living in an Age of Uncertainty*, Polity Press: 12.

<sup>3</sup> N.Luhmann 1982. *The Differentiation of Society*, Columbia University Press; N.Luhmann 1997. *Gesellschaft der Gesellschaft*, Suhrkamp.

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We welcome this opportunity to comment on the consultation paper on emerging biotechnologies. We hope that our comments will be helpful. Our comments relate solely to Questions 1-7,10, 14 and 17 of the consultation paper.

### **Preliminary Remarks**

We will confine our comments primarily to the legal issues which we feel emerge from the consultation paper, and discuss their relevance chiefly in relation to biomedical research.

#### **Question 1:**

In discussing the term ‘emerging biotechnology’ we feel that the focus of the working group should be on the ‘emerging’ nature of the technology. In this respect, the fact that the technology is emerging and developing means that its ultimate impact is uncertain. As a result of this uncertainty, the legal and ethical regulation of the technology must be sufficiently flexible to accommodate the uncertain and dynamic nature of the technological outcomes.

One way that this might be done is through the use of a system of regulation which provides for regular reviews of governance systems to accommodate developments in science and technology. Contemporary society is increasingly viewed as a network rather than a structure and an ‘infinite volume of permanent permutations’.<sup>2</sup> It is governed by a multitude of normative layers. Consequently, our definitions of governance are changing. There is an increased focus on the variety of techniques of governance being extended from law and politics to include economic, scientific, technological and ethical techniques, among others, which illustrates the change of focus from politico-legal institutions to the increasing significance of a variety of communicative functions or techniques.<sup>3</sup> In a governance system, balance should be sought between ossification and the need to avoid per se bans, against overly

permissive solutions, as well as different value systems and cultural norms. At the same time however, the flexibility of such a system of regulation should not lead to fragmentation and lack of transparency, and yet more uncertainty, which as aptly described by Z. Bauman (*Liquid times* 2007) is the fundamental feature of today's society.

### **Question 2:**

From our perspective, one of the key features of emerging biotechnologies is the fact that they tend to in some way affect or change our understanding of life (what J. Habermas calls a "self-understanding of the species"<sup>4</sup>). These technologies redefine our understandings and challenge our existing perspective of the definitions of species and the distinctions between what is synthetic and natural, and animal and human.

These are obviously important philosophical and ethical questions. They are also relevant to the English legal system which, in common with the majority of major legal systems, incorporates distinctions between "things" (chattels) and "persons". These distinctions are particularly pertinent in fields such as human rights, property and intellectual property law. For instance, intellectual property law depends to some extent on systems of classification of products or process as natural or synthetic, or human or non-human. "Emerging biotechnologies" not only challenge these frameworks, but question some of the principal assumptions on which they have been based.

### **Question 3:**

Academic research tends to focus on a consideration of the legal issues associated with an ever increasing range of 'new' or 'emerging' technologies. However, to a great extent, the legal issues raised by these new technologies are not in themselves new. There are a limited range of areas where there is a need for truly new legal regulation; for example, children born as a result of artificial reproductive technologies which allow for more than two biological parents raise truly novel questions, which will necessitate new legal rules. However, areas such as genomics or synthetic biology for example do not raise truly *new* legal issues. They might however make the existing problems more visible, change their internal dynamics or add an additional dimension. For instance, some medical information is predictive not only for an individual, but also for members of his or her family; advances in genetics and genomics made this relationship much more important and reinforced the rights of family members. Similarly, genomics coupled with digitisation of medical information adds gravity to the existing legal issues arising from data processing and data sharing. Therefore, "emerging biotechnologies" call for investigation of whether, and how, existing legal principles and regulation might apply within new fields of science.

In our submission, rather than focusing on the novelty of the technology, more in depth consideration of the legal issues that apply to all these fields of technology would be valuable. Such considerations should not be made in a vacuum, disregarding social and economic structures. Any evaluation should also take into account the

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<sup>4</sup> J. Habermas, *The Future of Human Nature*, Cambridge: Polity Press, 2003.

dynamic relationship between all the new technologies as well as between these technologies and other social phenomena.

### Questions 4-7

Social, cultural and political factors can have a highly influential role in the development of regulation of biotechnologies. The situation in Poland provides an illustrative example. Poland is best known for its very conservative and restrictive legal standpoint on abortion and the legal status of the human embryo. The abortion law embodied in the Act on Family Planning, Prenatal Life Protection and the Conditions under which Pregnancy Termination is Permitted 1993<sup>5</sup> has indeed been substantially influenced by Catholic doctrine and tradition. Interestingly, the fear of potential ostracism is so big that many doctors are reluctant to perform abortion even in cases permitted by law. The ECHR judgment in the case of *Alicja Tysiąc*<sup>6</sup> demonstrated that the enforcement of the already restrictive abortion provisions is still very problematic in every day practice. Especially in small rural communities doctors experience a lot of pressure from the Church and Catholic organisations, which get directly involved in patients' decision making processes.<sup>7</sup> It may seem that this approach is also reflected in the field of genetic testing. This presumption is, however, only partially correct.

It is interesting to note that to date, due to the polarisation of the political scene, the government has been postponing the regulation of assisted reproduction technologies for years. The attempt to avoid the confrontation of Catholic and conservative values with the liberal tradition and practice has discouraged politicians from taking any legislative initiative in this respect until very recently. For the same reason it has not yet managed to implement the EU directives 2004/23/EC, 2006/17/EC and 2006/86/EC on procurement, testing and storage of human in vitro cells and tissues.<sup>8</sup> Therefore, due to the lack of any provisions concerning the procedure of IVF, the legal status of the embryo *in vitro* remains unregulated.

The obligation to implement the above-mentioned EU directives and the pressure to ratify the Convention of Biomedicine and Human Rights (signed in 1999) forced the government to undertake the legal initiative to introduce the necessary changes to the existing law. In spring 2008 the Prime Minister appointed a special *ad hoc* bioethics committee to prepare the ratification of the Oviedo (Biomedicine) Convention. While it was chaired by a conservative MP Jarosław Gowin, who is a devoted opponent of in

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<sup>5</sup> Act on Family Planning, Prenatal Life Protection and the Conditions under which Pregnancy Termination is Permitted 1993 (Ustawa o Ustawie o planowaniu rodziny, ochronie płodu ludzkiego i warunkach dopuszczalności przerywania ciąży), 7.01.1993, (Dz.U. 1993 Nr 17 poz.78).

<sup>6</sup> ECHR, *Tysiąc v. Poland*, 20.03.2007 r., Application No 5410/03.

<sup>7</sup> Recently, a 14-year-old girl who had sought abortion was separated from her mother by a court decision (later revoked) and subjected to pressure from a priest and Catholic hospital manager. See: M. Bieleś, W Lublinie wrze. 14-latka chce aborcji, *Gazeta Wyborcza*, 11.06.2008, available at: [http://wyborcza.pl/1,91027,5300116,W\\_Lublinie\\_wrze\\_Czternastolatka\\_chce\\_aborcji.html](http://wyborcza.pl/1,91027,5300116,W_Lublinie_wrze_Czternastolatka_chce_aborcji.html). Retrieved on 3 May 2009.

<sup>8</sup> All available at: [http://www.dh.gov.uk/en/Publichealth/Scientificdevelopmentgeneticsandbioethics/Tissue/Tissuegeneralinformation/DH\\_4136920](http://www.dh.gov.uk/en/Publichealth/Scientificdevelopmentgeneticsandbioethics/Tissue/Tissuegeneralinformation/DH_4136920). Retrieved on 3 May 2009.

vitro fertilisation, the committee aimed at regulating issues such as assisted reproduction techniques. However, unsurprisingly, due to fundamental differences among members, the committee was not able to reach a consensus. As a result the final report presented to the Prime Minister in October 2008 consisted of two separate parts, offering two opposing viewpoints on every subject discussed by the members. Since then the Prime Minister has not been able to make a decision. Interestingly, in the meantime the ruling party formed another committee – this time in the Parliament – to regulate assisted reproduction techniques. Alternative legislative initiatives at both sides of the political scenes have been undertaken. A civic initiative, supported by the Catholic Church, aiming at an absolute ban on IVF has managed to collect 150000 signatures – much more than necessary for a bill to be discussed in Parliament. However, it has been rejected by the Parliament last year. For a moment Polish society had the chance to experience an open, transparent and fully informed debate about the issues of genetics, biotechnology and bioethics. However, this debate has been hindered by the economic crisis, Polish EU presidency, and forthcoming parliamentary elections.

Hence, in light of lack legally binding norms, pre-implantation genetic diagnosis is (at least in theory) permitted for all kinds of purposes, including sex selection and HLA tissue-typing. Since none of the ART and IVF practises are regulated, private clinics would be able to conduct all kinds of tests. The provisions of the Medical Provisions Act prohibiting any experiments with the so-called ‘conceived child’ do not apply, since PGD should be regarded as an experimental method anymore. The discussion currently taking place in the Polish literature focuses therefore on questions of whether IVF procedure can be considered a medical treatment and thus whether the state should contribute to it financially and finally, whether the right to procreation is an absolute human right or not (Haberko and Olszewski, 2008). However, the reason why Polish clinics are still not conducting PGD on a regular basis is that the procedure is still extremely expensive. All these issues are extremely fascinating as they reflect the exact state of the legal debate concerning assisted reproduction techniques in Poland. However, they all exceed the scope of this response.

## **Question 10**

As those who work in a university are well aware, research priorities for academic researchers are increasingly directed by the availability of funding. Research councils and charities assign priorities for funding, and although these calls are framed broadly, such funding priorities will result in some control of research direction, which necessarily affects later technological innovation.

Research in the sciences in academia is increasingly being focused on science with ‘translational outcomes’. It is true that science which has practical benefit is very worthwhile. But we, along with many others, would be concerned if this focus on translational research results in a lack of ‘blue skies’ research, from which many exciting innovations may ultimately develop. A 19<sup>th</sup> century German model of academia and knowledge production might be worth exploring. It is a model based on the idea of “*the unity of knowledge*: all insights are interconnected and belong to a universal structure which integrates and transcends specific disciplines. Our knowledge in its totality is an image of eternal knowledge comprises both the ideal and the real.” (Prichard, 1998).

We would also raise concerns about the profit motive and entrepreneurial focus in academic research. Whilst there is certainly a place for commercialisation of science, and we recognise the need for commercial development of therapies, there is also an important place for open academic research, unconstrained by concerns of industry. This may be particularly important in relation to early stage, upstream, or foundational research.<sup>9</sup>

#### Question 14

Research in emerging biotechnologies is a truly international endeavour, and involves researchers in many countries, often using samples and data from participants in many different countries. However, legal regulation occurs as a matter of national law. It is complex and time-consuming process to conduct such research in compliance not only with differing legal regimes, but also different ethical frameworks.

Despite many attempts to regulate this area, the global community has failed to establish international legal regime that deals comprehensively with the ‘technological revolution’.<sup>10</sup> At the same time, an increasing number of governmental and non-state actors have become significantly involved in the sector. Non-state actors especially, including a wide range of nongovernmental organisations, agencies, foundations, research and other professional networks, religious groups, and for-profit organisations such as the pharmaceutical industry, have had an increasingly powerful influence on international health policy and global lawmaking.<sup>11</sup> The members of this complex network use legal, political, and various other forms of decision-making that result in regulatory instruments of contrasting normative status.

Law created in this heterogeneous environment has been said to be developing in a fragmented, uncoordinated, amorphous, and hence inconsistent, inefficient, and incomplete manner.<sup>12</sup> Parallel to the multitude of actors, whose status can only inadequately be reassigned to well-known public/private distinctions, the biomedical world is witnessing the emergence of a large, decentralized and non-harmonized body of norms. What characterises law in this field at the international level is a general lack of legally binding norms – so-called ‘hard law’ – alongside an overwhelming proliferation of soft law instruments. Such a fractured legal process exacerbates uncertainties about the legal regime that governs biotechnological developments. This development can be seen as an impediment rather than an incentive for international scientific co-operation, making it extremely difficult for doctors, researchers, and

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<sup>9</sup> MA Heller and RS Eisenberg. Can Patents Deter Innovation? The Anticommons in Biomedical Research, *Science* 1998, 280: 698

<sup>10</sup> R. Brownsword. 2008. *Rights, Regulation and the Technological Revolution*, Oxford University Press.

<sup>11</sup> K. Buse, G. Walt, Global public–private health partnerships: Part I — a new development in health? *Bulletin of the World Health Organization* 2000, 78: 549–561 and K. Buse, G. Walt, Global public–private health partnerships: Part II — what are the issues for global governance? *Bulletin of the World Health Organization* 2000, 78: 699–709.

<sup>12</sup> A. Taylor. Governing Globalization of Public Health, *The Journal of Law, Medicine and Ethics* 2004, 500-508: 500, J.P Ruger, D. Yach. The Global Role of the World Health Organization, *Global Health Governance* 2008 /2009, 2:2.

private companies to determine which governance regime is applicable in any particular case, and which prevails when conflicts occur. It may also become confusing for national legislators, who, when trying to regulate particular problems, look for clear and coherent international guidelines. Many differences in the legal requirements at the national level remain and militate against networking. Consequently, the proliferation and specialization of laws leads to a multiplication of standards and terminology.<sup>13</sup> Quite apart from the varying interests of different societies, there are often ‘different starting points for the very idea of regulation’.<sup>14</sup>

Therefore, proposals have been formulated for more effective separation<sup>15</sup>, coordination<sup>16</sup>, or subsuming<sup>17</sup> of different regulatory remits. Indeed, claims have been made that a formalised, centralised, and institutionalised system would help address the problems of transparency and legitimacy and deal with bioethical issues at the international level more effectively. More study is required as to the need of a universal model/ framework of regulation and the theoretical foundations of different regulatory proposals as well as to the practical implications of each conceptualisation. At the same time, there is need for more social scientific investigation.

### Question 17

We feel that there is benefit in paying particular attention to public engagement activities in this field. The reason for this is that, as we indicated in our response to question 1, one of the key aspects of emerging biotechnologies is that they have implications for our understanding of the nature of life. Because understandings of the nature of life are so central to the core beliefs of a large proportion of members of society, it is important that public engagement in this field be thoughtful and sensitive. To fail to take into account social and moral concerns in this field risks a loss of trust in science, and the potential for a public backlash. Where there are public concerns about science, it is better that these concerns be addressed at an early stage, whether that be by changes to the way the science develops, or through increased public awareness of the true nature of what is being done. Public engagement can and should be a two way process, not only about educating the public, but also about informing and enhancing the scientific process.

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<sup>13</sup> B.M. Knoppers, M. H Abdul-Rahman, and K. Bédard, Genomic Databases and International Collaboration, *King's Law Journal* 2007; 18: 291–311; A. Cambon-Thomsen, C. Sallée, E. Rial-Sebbag and B.M. Knoppers, Populational Genetic Databases : Is a Specific Ethical and Legal Framework Necessary? *GenEdit* 2005; 3:1: 1-13; S. MC Gibbons, J. Kaye. Governing Genetic Databases: Collection, Storage and Use, *King's Law Journal* 2007; 18: 201–208.

<sup>14</sup> M.D. Kirby, 1999. *Human Freedom and Human Genome: The Ten Rules of Valencia*, cited by: R.Brownsword. 2008. *Rights, Regulation, and the Technological Revolution*, Oxford University Press: 295. Also: M.D. Kirby. The Human Genome Project – Promise and Problems, *Journal of Contemporary Health Law and Policy* 1994; 11:1.