Ethical EU law? The influence of the European Group on Ethics in Science and New Technologies

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The European Group on Ethics in Science and New Technologies (EGE) plays an ambiguous role in the European Union's legal order. Seen from the perspective of the on-going "democratic deficit" debate, EU regulation of biotechnology is problematic. The prize of European competitiveness mandates EU-level law and policy-making to enhance the expansion of the biotechnology industry. Yet a widespread citizen consensus for such expansion is lacking. The article shows that the EGE is significantly influential in bolstering the acceptance of emerging biotechnologies, by supplying authoritative normative endorsement to legislation and administrative activity that supports the activities of market actors within the biotechnology industry. But at the same time, the constitutional status of the EGE is at best "grey", given that it has no firm basis in the European Union's constituent Treaties, or the legislative structures developed to enhance the legitimacy, transparency, accountability, representativeness, effectiveness and efficiency of the European Union's legislative and executive decision-making.

Introduction

The European Union is committed to becoming a more competitive player in the global economy. A central plank of its revised Lisbon strategy towards this end is to increase and improve investment in research and development, to facilitate innovation, and to contribute to a strong European industrial base.[1] To achieve this, the European Union seeks to provide clear and predictable regulatory conditions for the technology-intensive forms of economic activity in which the economies of its Member States specialise.

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[1] Communication on Working together for growth and jobs—A new start for the Lisbon Strategy COM(2005) 24 final.

Among these, biotechnology is key for the European Union's future competitive development.[2]

Yet, as recognised by the European Commission since at least the early 1990s,[3] many biotechnologies central to this vision of economic growth are ethically contentious amongst the populations of the Member States of the European Union. In such circumstances, granting regulatory powers to the EU Commission is politically unacceptable. Moreover, the Commission lacks both the resources and the expertise to take detailed regulatory and administrative decisions in technical fields such as biotechnology. At the same time, however, the benefits of European integration, and thus the prize of global competitiveness, cannot be readily achieved without EU-level regulatory standards and administrative procedures.

In the 1970s and 80s, the main response to the lack of acceptable regulatory capacity in the European Commission (not only in the area of biotechnology) was comitology. Committees made up of national civil servants with specific expertise in an area and chaired by the Commission take decisions that are formally "technical" (but sometimes actually politically contested) under powers delegated by EU legislation.[4] In the 1990s and 2000s, while comitology procedures continue to be used, in addition, the European Union has become increasingly reliant upon agencies. These agencies are bodies made up of independent experts who engage with EU level policy formation and implementation, through various tasks ranging from information gathering and dissemination through to authorising the marketing of products as safe. The rise of agencies is thought to be linked to the increasing complexity of EU policy issues and questions of legitimacy of EU decision-making processes.[5] Several agencies are concerned, to a greater or lesser extent, with regulation of biotechnologies.[6]

Both comitology and EU-level agencies have been subject to debate concerning their democratic deficiencies.[7] Are decisions made by technical experts, without (much if any) attention to their political and social dimensions, and without recourse to representatives

[2] Communication on Promoting the competitive environment for the industrial activities based on biotechnology within the Community SEC(91) 629 final.

[3] See Communication on promoting the competitive environment, pp.1–2, where the Commission emphasised the need for ethical discussions on the development of biotechnology: "it is imperative that problems of public acceptability, and ethical questions raised, be recognised and dealt with. It is suggested that there should be advice available to the Commission in the area of ethics in biotechnology."

[4] See, e.g. M. Andenas and A. Turk (eds), *Delegated Legislation and the Role of Committees in the EC* (London: Kluwer Law International, 2000); C. Joerges and E. Vos (eds), *EU Committees: Social Regulation, Law and Politics* (Oxford: Hart Publishing, 1999); R. Dehousse, "Comitology? Who watches the watchmen?" (2003) 10 J.E.P.P. 798; T.K. Hervey and J.V. McHale, *Health Law and the European Union* (Cambridge: Cambridge University Press, 2004), p.50.

[5] See, e.g. G. Majone, *Regulating Europe* (London, New York: Routledge, 1996); R. Dehousse, "Regulation by Networks in the European Community: the Role of European Agencies" (1997) 4 J.E.P.P. 276; E. Vos, "Reforming the European Commission: What Role to play for EU Agencies" (2000) 37 C.M.L. Rev. 1113; Craig, *EU Administrative Law* (Oxford: OUP, 2006), pp.145–148; E. Chiti, "Decentralisation and Integration into the Community Administrations: A New Perspective on European Agencies" (2004) 10 E.L.J. 402; D. Geradin, R. Muñoz and N. Petit, *Regulation through Agencies in the EU: A New Paradigm of European Governance* (Aldershot: Edward Elgar, 2006).

[6] These include the European Environmental Agency, the European Agency for the Evaluation of Medicinal Products, the Community Plant Variety Office and the European Food Safety Authority.

[7] See, for instance, C. Harlow, *Accountability in the European Union* (Oxford: OUP, 2002); C. Scott, "Accountability in the Regulatory State" (2000) 27 *Journal of Legal Studies* 38; Andenas and Turk (eds), *Delegated Legislation and the Role of Committees in the EC*; Joerges and Vos (eds), *EU Committees*;

of the wider EU citizenry, democratically legitimate? Are the members of committees and agencies sufficiently accountable for their decisions, either through legal or political processes? Are their activities sufficiently transparent? Are general principles of EU administrative law, such as limitations on the powers of the Commission to delegate executive tasks,[8] sufficient to ensure legitimacy? Partly in response to these concerns, the European Union has moved towards developing formalised legal controls over committees and agencies.[9]

However, alongside these more formalised bodies, within the European Union's regulatory structures there are informal bodies whose public law status is much cloudier. One example of these "grey government" bodies is the European Group on Ethics in Science and New Technologies (EGE).[10] This article considers the ways in which the EGE has influenced legislative and administrative processes within the European Union, and suggests that these show a potential for continued and significant influence in the future. However, unlike committees or agencies, the EGE has very scant constitutional basis in EU law. If we take seriously the idea that the European Union's regulatory activities are legitimated by a (partial, but nonetheless significant) legal constitutional structure, then the lack of clarity of the constitutional position of bodies such as the EGE is a problem for EU law.

The article proceeds as follows. We first explain the origins of the EGE, its mandate and its membership. The main body of the article shows, through three examples, the ways in which the EGE has influenced EU legislative and administrative processes. The article draws on the documentary record and on semi-structured interviews with six current and former members of the EGE and with the former and current head of the EGE

M. Shapiro, "Problems of Independent Agencies in the United States and European Union" (1997) 4 J.E.P.P. 276; P. Lindseth, "Democratic Legitimacy and the Administrative Character of Supranationalism: The Example of the European Community" (1999) 99 *Columbia Law Review* 628; G. Lindseth, "Weak constitutionalism? Reflections on comitology and transnational governance in the European Union" (2001) 21 *Oxford Journal of Legal Studies* 145; G. Majone, *Dilemmas of European Integration: The Ambiguities and Pitfalls of Integration by Stealth* (Oxford: OUP, 2005); R. Dehousse and C. Joerges, *Good Governance in an Integrated Market* (Oxford: OUP, 2002); C. Joerges, "Integration through de-legalisation" (2008) 33 E.L. Rev. 291; F. Scharpf, *Governing in Europe. Effective and Democratic?* (Oxford: OUP, 1999); R. Dehousse, "Regulation by Networks in the European Community: the role of European agencies" (1997) 4 J.E.P.P. 246; A. Arnull and D. Wincott, *Accountability and Legitimacy in the European Union* (Oxford: OUP, 2002); D. Geradin and N. Petit, "The Development of Agencies at EU and National Levels: conceptual analysis and proposals for reform (Jean Monnet Working Paper 01/04)" (2004) 23 Y.E.L. 137.

[8] See *Meroni & Co Industrie Metallurgiche SpA v High Authority of the European Coal and Steel Community* (C-9/56) [1958] E.C.R.133.

[9] Decision 1999/468 laying down the procedures for the exercise of implementing powers conferred on the Commission [1999] OJ L184/23; Decision 2006/512 amending Decision 1999/468 laying down the procedures for the exercise of implementing powers conferred on the Commission [2006] OJ L200/11; Communication on the operating framework for the European regulatory agencies COM(2002) 718 final; Regulation 58/2003 laying down the statute for executive agencies to be entrusted with certain tasks in the management of Community programmes [2003] OJ L11/1; Regulation 168/2007 establishing a European Union Agency for Fundamental Rights [2007] OJ L53/1.

[10] The EGE was formerly known at the Group of Advisers to the European Commission on the Ethical Implications of Biotechnology (GAEIB). For the purposes of this article, the GAEIB and the EGE are treated as the same group, although at different stages in its development.

Secretariat.[11] We conclude with a brief discussion of the constitutional position of the EGE.

What and who is the EGE?

The EGE began as a modest ad hoc advisory body, the Group of Advisers to the European Commission on the Ethical Implications of Biotechnology (GAEIB). It has grown incrementally in both size and scope, to include wider expertise and more established members. With six members at its inception, the GAEIB expanded to nine in 1994. The EGE, established in 1998, had 12 members, increased to 15 in 2005. The members of GAEIB (1991–1997) came from the disciplines of law, science, medicine, philosophy and theology. From 1998, the disciplines included sociology and informatics. Members of the GAEIB served terms of two years, the members of the EGE in 1998–2000 served three, and members now serve for five years. These changes have enabled the EGE to address a wide range of ethical issues, and to speak with an increasingly authoritative voice.

One problem with research into the EGE is that most published statements on its status and mandate are self-generated.[12] The EGE sees itself as enabling,

> "the Community authorities, which are responsible for regulating the market, to take better account of the aspirations of the public in the various aspects of their lives: as consumers, workers, parents, patients etc".[13]

While under the chairmanship of Noëlle Lenoir, the EGE seemed keen to gain a more official status, recognising that mere attention does not in itself play a legitimating role.[14] However, the current head of the EGE Secretariat, Maurizio Salvi, does not see any lack of clarity concerning the status of the EGE, as an independent advisory body.[15]

[11] Focused, semi-structured interviews were held with six former and current members of the EGE. Additional interviews were held with the former and current Head of the EGE Secretariat, who represent the EGE in the Bureau of European Policy Advisers (BEPA), which advises the President and Commission Services on issues relevant to the President's agenda and the future of policies in the Union. Interviews were translated (where necessary), transcribed and analysed to elucidate the legal and political norms articulated by the EGE in the context of the commercialisation of human tissues and cells. These interviews enabled us to access a more detailed account of the trajectory of decision making and influence of the EGE than would otherwise have been possible.

[12] The mandates on the website, up until the latest one, were written by the Chair of the time, as are the rules of procedure. Most documents or statements made about the EGE are rather subjective.

[13] *General Report of the Activities of the European Group on Ethics* (Brussels: 1998–2000), p.12, available at *http://ec.europa.eu/european_group_ethics/archive/1998_2000/activities_en.htm* [Accessed October 1, 2008].

[14] "One thing, however, is clear: it is high time to put an end to the current, paradoxical situation. On the one hand, the EGE is increasingly well known outside the Commission. International general and specialised media regularly report on its work. Students write dissertations and theses examining its work. When the Group pays its traditional six-monthly visit to the country holding the EU presidency, it is received by the highest national authorities. Yet it does not have genuine recognition within the Commission. Its status remains uncertain. A Community decision should enable it to be given a more official and, at the same time, clearer status." See, *General Report on the Activities of the European group on Ethics in Science and New Technologies to the European Commission 1998–2000*, p.24, available at *http://ec.europa.eu/european_group_ethics/archive/1998_2000/activities_en.htm* [Accessed October 1, 2008].

[15] Interview Maurizio Salvi, June 20, 2007.

The remit and responsibilities of the EGE have developed with each successive mandate. The GAEIB's first mandate (1991–1993) followed a Commission Communication mentioning the need for expert advice in biotechnology.[16] The Commission's difficulties with Directive 98/44 were also significant.[17] There is no official documentary statement on this mandate, but the EGE's website[18] states that the rationale for establishing the GAEIB was to support the regulatory process.[19]

A somewhat more nuanced rationale behind the establishment of the GAEIB is evident in the Communication on promoting the competitive environment for industrial activities based on biotechnology within the Community.[20] The Communication states that:

> "It is desirable that the Community have an advisory structure on ethics and biotechnology which is capable of dealing with ethical issues where they arise in the course of Community activities ... The Commission considers that through addressing explicitly the ethical challenges, it is helping to improve the climate of public understanding and opinion concerning the responsible development of biotechnology; hence facilitating the acceptance of its benefits, and ensuring a single market for its products."[21]

In other words, in order to harness the economic benefits of a burgeoning knowledge economy, the European Union needed to reconcile scientific and technological innovation as a necessary impetus for European advancement while at the same time safeguarding the manifold values upon which European identity has been built.[22] There is also an educational role to be played here, in improving public understanding of biotechnologies, and thus, it is implied, their acceptance.[23]

[16] See Communication on promoting the competitive environment SEC(91) 629 final.

[17] See below.

[18] "[T]o identify and define the ethical issues raised by biotechnology; to assess, from the ethical point of view, the impact of the Community's activities in the field of biotechnology; to advise the Commission, in the exercise of its powers, on the ethical aspects of biotechnology and to ensure that the general public is kept properly informed." See the EGE website at *http://ec.europa.eu/european_group_ethics/archive/1991_1997/organisation_en.htm* [Accessed October 1, 2008].

[19] "Biotechnology is not only a vital sector of European research and industry. It is inevitably a source of large amounts of legislation: directives on the use of genetically modified organisms, proposed directives on the legal protection of biotechnological inventions, etc. This legislation cannot ignore the ethical dimension. This was what prompted the European Commission on 20 November 1991 to set up a group of advisers on the ethical implications of biotechnology." See the EGE website at *http://ec.europa.eu/european_group_ethics/archive/1991_1997/index_en.htm* [Accessed October 1, 2008].

[20] See Communication on promoting the competitive environment for the industrial activities based on biotechnology within the Community SEC(91) 629 final.

[21] Communication on promoting the competitive environment for industrial activities based on biotechnology within the Community SEC(91) 629 final, p.16.

[22] *General Report on the Activities of the European Group on Ethics in Science and New Technologies to the European Commission 1998–2000*, p.9 available at *http://ec.europa.eu/european_group_ethics/archive/1998_2000/activities_en.htm* [Accessed October 1, 2008]; see also G. Hermeren, "Value conflicts and the integration of Europe", in *General Report of the Activities of the EGE: 2000–2005 (2005)* available at *http://ec.europa.eu/european_group_ethics/archive/2001_2005/activities_en.htm* [Accessed October 1, 2008].

[23] In 1994, a press release (IP/94/153) available at *http://europa.eu/rapid/pressReleasesAction.do?reference=IP/94/153&format=HTML&aged=1&language=EN&guiLanguage=en* [Accessed October 1, 2008] on the GAEIB's second term stated that its role would be strengthened according to the recommendations of the European Commission's White Paper on growth, competitiveness and employment: The challenges and ways forward into the 21st century COM(93) 700 final A and B. However, for the most part it seems that their remit remained relatively unchanged.

A Commission Communication established the European Group on Ethics in Science and New Technologies (EGE), in December 1997.[24] The EGE's remit expanded to include communications and information technology. The Parliament and the Council of Ministers were also given power to request Opinions.[25] The expanding role of the EGE, as compared to the GAEIB, is evident from the 1998 description of the main objectives of the EGE by Commission President Jacques Santer. These include,

> "to help break down barriers in fields which require a multi-disciplinary approach, not only scientific and legal but also philosophical, sociological and economic";
>
> "to provide European decision-makers with clear and up-to-date basic information, enabling them to be properly informed in carrying out their duties";

and,

> "to promote dialogue that stimulates mutual tolerance so that all viewpoints can be expressed before the Community authorities decide on appropriate regulations".[26]

In this description, the EGE is the servant of "European decision-makers", not solely the Commission.[27] Whereas the GAEIB's task was simply to keep the European Union's citizens informed, the EGE has an expanded role of promoting dialogue and actively encouraging at least tolerance and ideally acceptance of new areas of technology.

The EGE's mandate for 2000–2005 was also established by nothing more formal than a Commission Communication.[28] The major change at this stage was that the EGE secretariat were integrated in the Bureau of European Policy Advisors, reporting directly to the President of the Commission and acting under his authority. A Commission Decision[29] of May 2005 marks the first formal legal document establishing a mandate (2005–2009) for the EGE. From this time on, a list of EGE Members is published in the Official Journal.[30] The EGE's remit, however, remained the same. Formally speaking, this mandate is,

> "to advise the Commission on ethical questions relating to sciences and new technologies, either at the request of the Commission or on its own initiative. The

[24] Communication establishing the European Group on Ethics in Science and New Technologies (EGE) SEC(97) 2404.

[25] See *General Report on the Activities of the European group on Ethics in Science and New Technologies to the European Commission 1998–2000*, p.7, available at *http://ec.europa.eu/european_group_ethics/archive/1998_2000/activities_en.htm* [Accessed October 1, 2008].

[26] See the EGE website at *http://ec.europa.eu/european_group_ethics/archive/1998_2000/intro_en.htm* [Accessed October 1, 2008].

[27] Although as we will see, this position is less clear in the legislative texts on which the EGE is based, in which the access of the other institutions to the EGE is mediated through the Commission.

[28] "This text describing the remit of the European Group on Ethics in Science and New Technologies shall replace the remit annexed to the Communication to the Commission of 12 December 1997 on the establishment of the European Group on Ethics in Science and New Technologies": Communication on the establishment of the European Group on Ethics in Science and New Technologies SEC(97) 2404.

[29] Decision 2005/383 on the renewal of the mandate of the European Group on Ethics in Science and New Technologies [2005] OJ L127/17.

[30] Decision 2005/754 on the appointment of the members of the European Group on Ethics in Science and New Technologies for its third mandate [2005] OJ L284/6.

> Parliament and the Council may draw the Commission's attention to questions which they consider to be of major ethical importance".[31]

In practice, as noted above, "advising" the Commission has wider implications, in particular in terms of promoting biotechnology as a safe and ethically robust part of the European Union's developing economy.

The EGE's advice to the Commission, Parliament and Council takes the form of written Opinions.[32] The EGE/GAEIB has issued some 23 Opinions, at the rate of one or two each year. These include Opinions on EU agriculture[33] and food law, such as on use of performance-enhancers in agriculture and fisheries,[34] animal cloning for food supply,[35] and on the labelling of the food derived from modern biotechnology.[36] They include Opinions on biomedical matters, such as on gene therapy,[37] prenatal diagnosis,[38] human tissue banking,[39] umbilical cord blood banking,[40] nanomedicine,[41] and on matters relating to biotechnological research that might have medical applications in the future, such as on genetic modification of animals,[42] cloning techniques,[43] on human stem cell research and use[44] and on intellectual property rights in biotechnological inventions.[45] Three Opinions concern the European Union's "Framework" research funding programmes[46] and one covers clinical research in developing countries.[47] There is also an Opinion on doping in sport,[48] and one on "healthcare in the information society".[49] The EGE's Opinions cover the main areas in the field of bioethics.[50]

[31] Decision 2005/383 on the renewal of the mandate of the European Group on Ethics in Science and New Technologies [2005] OJ L127/17 Art.2.

[32] For the full text of all the Opinions, see EGE website at *http://ec.europa.eu/european_group_ethics/avis/index_en.html* [Accessed October 1, 2008].

[33] It is currently working on an opinion in modern developments in agriculture technologies, see the EGE website at *http://ec.europa.eu/european_group_ethics/index_en.htm* [Accessed October 1, 2008].

[34] Opinion No.1 on the ethical implications of the use of performance enhancers in agriculture and fisheries (1993).

[35] Opinion No.23 on the Ethical Aspects of animal cloning for food supply (2008).

[36] Opinion No.5 on the ethical Aspects of the labelling of food derived from modern biotechnology (1995).

[37] Opinion No.4 on the ethical implications of gene therapy (1994).

[38] Opinion No.6 on the ethical aspects of prenatal diagnosis (1996).

[39] Opinion No.11 on the ethical aspects of human tissue banking (1998).

[40] Opinion No.19 on the ethical aspects of umbilical cord blood banking (2004).

[41] Opinion No.21 on the ethical aspects of nanomedicine (2007).

[42] Opinion No.7 on the ethical aspects of genetic modification of animals (1996).

[43] Opinion No.9 on the ethical aspects of cloning techniques (1997).

[44] Opinion No.15 on the ethical aspects of human stem cell research and use (2000).

[45] Opinion No.3, an Opinion on ethical questions arising from the Commission proposal for a Council directive for legal protection of biotechnological inventions (1993); Opinion No.16 on the Ethical aspects of patenting involving human stem cells (2002).

[46] Opinion No.10 on the ethical aspects of the Fifth Research Framework Programme (1997); Opinion No.12 on the ethical aspects of research involving the use of human embryo in the context of the Fifth framework programme (1998); and Opinion No.22 on the ethics review of hESC FP7 research projects (2007).

[47] Opinion No.17 on the ethical aspects of patenting inventions involving human stem cells (2003).

[48] Opinion No.14 on the ethical aspects arising from doping in sport (1999).

[49] Opinion No.13 on the ethical issues of healthcare in the information society (1999).

[50] F.D. Lafond, "Towards a European Bioethics Policy? Institutional structuring and political responses" in M. Steffen (ed.), *Health Governance in Europe: Issues, Challenges and Theories* (London and New York: Routledge, 2005).

The EGE's influence

Why should we be interested in the EGE? One reason is its influence on EU law and policy-making processes. Three illustrative examples[51] concern intellectual property in biotechnological inventions; the use of human tissues and cells in medicine; and human embryonic stem cell research.

The EGE's role in the adoption of Directive 98/44 on the legal protection of biotechnological inventions

Directive 98/44[52] on the legal protection of biotechnological inventions, originally proposed in 1988, was adopted 10 years later, largely because of the highly controversial ethical debates surrounding the Directive, concerning not only patent law, but also biotechnology in general. The original Commission proposal was explicitly related to the European Union's need to keep pace with the United States and Japan, who were dominating the world market in biotechnology.[53] However, concerns that the Commission was paying insufficient attention to the ethical implications of its proposal were raised,[54] in particular by the European Parliament.[55] Parliament rejected the original proposal[56] in 1995, due mainly to differing interpretations of the "ethical problems" at hand, in particular, relating to the patentability and genetic manipulation of various elements of the human body.

Patenting, the core of the Biotechnology Directive, was the first biotechnological issue to be addressed in legislation by the European Union. Consequently, the host of ethical issues raised by biotechnologies more broadly served to intensify the ethical debates surrounding the Directive. This was a significant moment in EU constitutional law, as

[51] Other examples can be seen: Directive 2001/18 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220 [2001] OJ L106/1 Art.29: "Without prejudice to the competence of Member States as regards ethical issues, the Commission shall, on its own initiative or at the request of the European Parliament or the Council, consult any committee it has created with a view to obtaining its advice on the ethical implications of biotechnology, such as the European Group on Ethics in Science and New Technologies, on ethical issues of a general nature." The institutions discuss the need to consult the EGE in recital 57. The EGE has not discussed this area, and so their opinions could not be regarded in this context, but they are seen as the relevant authority which should be consulted.

[52] Directive 98/44 on the legal protection of biotechnological inventions [1998] OJ L213/13.

[53] For example a report by the OECD in 1985 said that of its members these two countries were the only ones with adequate legislation on biotechnology. Figures shown from during the debates on this Directive also show this emphasis on the US and Japan, with the US being where 65% of all biotechnology patents originated in 1996.

[54] See for example Opinion of the Economic and Social Committee on the Proposal for a Council Directive on the legal protection of biotechnological inventions [1989] OJ C159/10. The Economic and Social Committee in 1989 criticised the Proposal as too legal and technical without enough consideration of ethical questions. The report criticised the Commission saying it did not "face up to all the issues" and that they regretted that "human beings per se are not expressly mentioned in the Directive as not being patentable".

[55] The main issues of debate revolved particularly around the question of the patentability of parts of the human body and the genetic manipulation of the human body. The Parliament was reacting to what it saw as the public's concerns in the area of biotechnology.

[56] Duly debated and amended, see Amended proposal for a Directive on the legal protection of biotechnological inventions COM(92) 589; [1993] OJ C44/36; Common Position No.4/94 adopted by the Council on February 7, 1994 with a view to adopting Directive on the legal protection of biotechnological inventions [1994] OJ C101/65.

it was the first time the Parliament had exercised its veto power under the co-decision procedure.[57] A new proposal[58] was finally adopted in 1998.[59]

In part in response to the ethical debate surrounding the Directive, GAEIB was created in 1991. The GAEIB adopted two early Opinions that influenced the development of the Directive and the terms on which it was eventually adopted.[60] These were GAEIB Opinion No.3 on ethical questions arising from the Commission proposal for a Council directive for legal protection of biotechnological inventions and GAEIB Opinion No.8 on Ethical Aspects of patenting inventions involving elements of human origin.

(a) Opinion No.3

Opinion No.3, published in September 1993, responded to the fact that discussions on the Directive were more about ethics than about law or economics. The Opinion specifically examines ethical questions on the legitimacy of patenting living matter; protecting human dignity; transgenic animals; and biodiversity. The Opinion concludes that,

> "there are no ethical objections to the patenting of biotechnological inventions *per se*; and that, furthermore, in pursuit of its economic and social objectives, it is essential for the Community to harmonize patent law relating to biotechnology".[61]

The Opinion acknowledges ethical questions raised by biological and genetic research and related applications and proposes their inclusion in the recitals of the Directive. As these ethical issues had never previously arisen in the field of EU patent law, the Opinion urges clarification of concepts and of the scope of provisions in the Directive. On human dignity, the Opinion advises that "genes and partial gene sequences whose functions are unknown should be made expressly unpatentable"[62] and, to this end, urges the European Union to oppose commercial exploitation of the human body. In spite of the 1993 Parliamentary resolution[63] condemning the production of transgenic animals

[57] Article 251 EC.

[58] Proposal for a Directive on the legal protection of biotechnological inventions [1996] OJ C296/4. Again this was amended, the European Parliament managed to pass a number of amendments and at this late stage of development in the Directive, the Commission agreed to 65 of the 66 amendments proposed by the Parliament only rejecting one because of it being unworkable: a new Article which stated that a patent cannot be issued if the inventors either failed to obtain fully informed consent for the use of human biological material or failed to list the geographic origin of other biological material and proved that material was removed from the country of origin in accordance with the law. The Council later reinforced this rejection. For further discussion see E. Cloatre, "From international ethics to European Union policy: a case study on biopiracy in the EU's Biotechnology Directive" (2006) 28(3) *Law and Policy* 345.

[59] Directive 98/44.

[60] See Proposal for a European Directive on the legal protection of biotechnological inventions COM(97) 446 final, Co-decision procedure [1997] OJ C286/87, which refers to Report No.8 by the Group of Advisers on the Ethical Implications of Biotechnology. See Opinion Economic and Social Committee [1996] OJ C295/11 para.3.2; the Economic and Social Committee asked the other institutions to have regard to the views of the "Group of Councillors for Ethics in Biotechnology". See also the final Common Position adopted by the Council, Common Position 19/98 acting in accordance with the procedure referred to in Art.189b of the Treaty establishing the European Community with a view to adopting a Directive on the legal protection of biotechnological inventions [1998] OJ C110/17, Recital 19: "Account has been taken of Opinion No.8 of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission." Later opinions, such as Opinion Nos 9 and 10 also address ethical issues relevant to the Biotechnology Directive and were released prior to the Directive's publication.

[61] Opinion No.3, p.9.

[62] See Opinion No.3, p.9.

[63] Resolutions B3-0199, 0220 and 0249/93 on the first European Patent on animals [1993] OJ C72/127.

outright and calling for a moratorium on granting further applications for animal patents, the GAEIB did not propose a complete ban. It instead cautioned that,

> "extreme care must be taken to ensure that they [transgenic animals] are used for adequate purposes, do not suffer inadequate pain or cause damage for the general public".[64]

(b) Opinion No.8

Following the European Parliament's rejection of the amended proposal for the Directive, in April 1996 the European Commission again requested the GAEIB's Opinion. In the development of its Opinion No.8, the GAEIB took into account[65] the legislative proposal,[66] the European Parliament public hearing in June 1996, and the Economic and Social Committee Opinion.[67] The GAEIB also organised its own hearing with Members of the European Parliament, experts and representatives of industry, research, patients and environment associations.[68]

The Opinion, published in September 1996, suggests that the GAEIB draws the concepts of "ethics" widely, to include what might be considered technical legal concerns. To this end, the Opinion states that criteria determining patentability, such as the usual technical requirements of novelty, inventive step and industrial application,[69] must also be considered in the ethical context of whether they infringe human rights and respect for human dignity.[70] The GAEIB recognises an ethical dimension in the distinction between a biotechnological *discovery* (not patentable) and an *invention* (patentable) and consequently reasons that "knowledge of the complete or partial structure of a gene cannot be patented" as it relates to scientific discovery rather than invention.[71] While elements of human origin are excluded from patentability on technical legal grounds, the GAEIB also considers them ineligible on ethical grounds relating to the non-commercialisation of the human body. Thus persons from whom the samples were retrieved are not eligible for remuneration.[72] Likewise, the samples must be obtained with the free and informed consent of the donor.[73] Inventions developed from the knowledge of human genes, including a partial gene sequence, are patentable only if,

> "on the one hand, the identification of the function attached to a human gene, or a partial human gene sequence allows new possibilities (for instance the production of

[64] Opinion No.3, p.9.
[65] Opinion No.8 on ethical Aspects of patenting inventions involving elements of human origin (1996), p.1.
[66] Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions COM(95) 661 final [1996] OJ C296/4.
[67] Economic and Social Committee Opinion [1996] OJ C295/11.
[68] Held on June 24, 1996.
[69] Convention on the Grant of European Patents (European Patent Convention) of October 5, 1973 Art.52(1) available at *http://www.epo.org/patents/law/legal-texts/html/epc/1973/e/ma1.html* [Accessed October 1, 2008].
[70] Opinion No.8 para.2.1.
[71] Opinion No.8 para.2.2.
[72] Opinion No.8 para.2.3.
[73] Opinion No.8 para.2.4.

> new drugs), and, on the other hand, if the intended use of the patent is sufficiently specific and identified".[74]

Finally,

> "the affirmation of the citizens' rights in the European Union implies that the economical advantages derived from biotechnological developments should in no way affect the respect of ethical requirements".[75]

Here, although the GAEIB asserts that ethical principles aimed at preserving citizens' rights must not be compromised, its role in supporting the Commission to derive economic advantages through biotechnological inventions is openly acknowledged.

This line of reasoning appears more strongly in the later (2002) Opinion No.16 of the EGE on ethical aspects of patenting inventions involving human stem cells.[76] The need to keep the research field moving, implicit in the earlier Opinions, is expressed more strongly and weighs heavily:

> "One option would have been to forbid patenting of stem cells or stem cell lines. The consequence of such an option would be the major slowing of this research field (except in case of a very unlikely large public investment), and the EGE opinion is that it would be contrary to public (and especially patients') interests."[77]

The GAEIB Opinions are reflected in the final text of Directive 98/44. Article 6 creates an *ordre public* or morality clause[78] for inventions that are unpatentable, and specifies certain areas of research which automatically fall into this category: processes for cloning or modifying the germ line genetic identity of human beings, the use of human embryos for industrial or commercial purposes, and processes modifying the genetic identity of animals which would cause suffering without providing substantial medical benefit to humans or animals resulting from these processes. The categories in Art.6 of the Directive map to those identified by the GAEIB Opinions. The latter category relates specifically to the GAEIB's Opinion that there is no need for a complete ban on the production of transgenic animals.[79] The ethical principles outlined in Opinions Nos 3 and 8 are also mirrored in the Directive's recitals, especially recital 16, as suggested in Opinion No.3.[80] Chapter II of the Directive, entitled "Scope of Protection", may also be seen as a response to Opinion No.3's request for clarification of the Directive's scope. In addition,

[74] Opinion No.8 para.2.5.

[75] Opinion No.16 para.2.7.

[76] The EGE explains that, "the Group again insists on the necessity to avoid the granting of too broad patents that would impair further research and development": Opinion No.16 para.2.7.

[77] Opinion No.16 para.2.1.

[78] *Ordre public* is concerned with the protection of public security and the physical integrity of individuals as part of that society. Morality is the degree of conformity to moral principles that prevail in a given society. Both *ordre public* and morality are open to legislative interpretation in different cultures and countries and change over time according to the prevailing legal, political and social norms of the Member States. Accordingly, differences in interpretation of *ordre public* and morality have resulted in the implementation of contrasting and sometimes contradictory legislation both across the EU and within Member States.

[79] See Opinion No.3, p.9.

[80] "[A]cknowledges the ethical questions raised by biological and genetic research and related applications and proposes their inclusion in the recitals of the Directive": Opinion No.3, p.9.

the Directive explicitly names the EGE[81] and acknowledges that "account has been taken of Opinion No 8".[82]

It is probably not too much to say that, without the ethical stamp of approval from the GAEIB/EGE, Directive 98/44 might never have been adopted. The debate in the European Parliament opened the flood gates for consideration of concerns beyond the specifics of patenting covered by the proposal. For the European Parliament, the Directive embodied "all of the public's worries about biotechnology, eugenics and dignity".[83] In responding to the general public concerns about biotechnology, Parliament and the Commission risked going beyond the scope of this particular Directive. Suggested amendments for banning patenting of the human body and its components were very broad and ignored the fact that patents had previously been issued on extracted and isolated human biological materials.[84] The intense public debate on broader ethical concerns was addressed by the GAEIB, which then smoothed the path of the legislation. It is no wonder that the terms of the Directive reflect the GAEIB's Opinions.

Moreover, it seems that the EGE continued to influence the Directive's implementation and interpretation. For instance, the influence of the EGE's Opinions can be seen in the evolving interpretation and application of Art.6 of the Directive. The granting of a patent to Biocyte for the isolation and cryo-preservation of umbilical cord blood sparked a widespread and intensive ethical debate about commercialisation of the human body.[85] The patent was eventually successfully challenged[86] in April 2003,[87] in a decision based on the technical legal ground that the process was not novel, rather than on ethical grounds, for instance, *ordre public*. This may have been in part because *ordre public* is a difficult basis on which to sustain a legal argument. The French term *ordre public* is not directly translatable into other languages, and thus it carries different meanings in

[81] Directive 98/44 Art.7.

[82] Directive 98/44 recital 19.

[83] R. Gold and A. Gallochat, "The European Biotech Directive: Past as Prologue" (2001) 7(3) E.L.J. 331, 339.

[84] For instance, in a high profile and controversial decision in 1996, the European Patent Office in Munich granted the US-based company Biocyte a Europe-wide patent (EP 343217) for the isolation and cryo-preservation of umbilical cord blood. While the blood itself cannot be patented, Biocyte was in fact patenting the technique by which the cord blood is extracted and preserved, and its therapeutic uses upon thawing. E.A. Boyse, H.E. Broxmeyer et al., *Isolation and Preservation of Fetal and Neonatal Hematopoietic Stem and Progenitor Cells of the Blood* [1989/48], Application No.89900042.6 (Application date November 10, 1988, European Patent Office, Munich); see Gold and Gallochat, "The European Biotech Directive: Past as Prologue" (2001) 7(3) E.L.J. 331, 339.

[85] See further below.

[86] By Eurocord (an international registry for cord blood transplantation), the European Campaign on Biotechnology Patents (a coalition of European NGOs), Thermogenesis Corp, Christoph Then, the European Group for Blood and Marrow Transplantation (EBMT), the Green Party of Europe and Stichting Netcord Foundation, EUROTRANSPLANT.

[87] When the European Patent Office's Technical Board of Appeal ruled that, "the subject matter of the claims defended by the patent proprietor was not new vis-à-vis the state of the art and as such failed to meet the novelty requirement under Article 54 of the European Patent Convention". (Case No.T 0919/99-3.3.4 of April 7, 2003, Boards of Appeal of the European Patent Office available at *http://legal.european-patent-office.org/dg3/biblio/t990919eu1.htm* [Accessed October 1, 2008]. See also European Patent Office Press release available at *http://www.epo.org/about-us/press/releases/archive/2003/07042003.html* [Accessed October 1, 2008].) This followed the disclosure of an article (K. Koike, "Cryopreservation of pluripotent and committed hemopoietic progenitor cells from human bone marrow and cord blood" (1983) 25 *Acta Paediatr Japonica* 275) that reported the use of a process of isolation and cryo-preservation comparable to that found in the patent in suit.

different cultural, historical and regional contexts. The numerous interpretations prompted the Nuffield Council[88] to suggest that the EGE develop a standardised definition of *ordre public*.

In 2002,[89] the EGE published Opinion No.16 on the ethical aspects of patenting inventions involving human stem cells. In developing its Opinion, the EGE again faced the ethical dilemma of balancing the interests of the inventor with those of broader society, as patents can both encourage scientific progress to the benefit of better health care yet impair access to that health care due to the need for a licence and payment of fees to the patent holder. The Opinion aims to define the ethical conditions required for patentability including the ethical consideration of the limits of patenting human stem cells and the relevant processes enabling ethical evaluation. It recommends that stem cells, both embryonic and non-embryonic, be considered non-patentable except if genetically modified or modified by *in vitro* treatments.[90] However, *processes* involving stem cells, whatever their source, are considered to be patentable, exclusive of cloning. The implication is, were the process at issue in the *Biocyte* example to be considered under Directive 98/44, they would probably be considered to be patentable (if novel, involving an inventive step, and industrial application) and not contrary to *ordre public*.

The GAEIB/EGE obviously influenced Directive 98/44. The reasoning of the EGE's Opinions on patenting biotechnologies is evidently linked to the shaping of the final version of the Directive. The EGE offers brokerage between the concerns of European publics and the need to develop a healthy EU biotechnology research industry, appropriately protected by intellectual property rights. EGE Opinions may also relate to the subsequent interpretation of the Directive, particularly in clarifying the terms of which areas of biotechnology would be deemed unpatentable.

The legal protection of biotechnological inventions involving the use of human tissues and cells overlaps to some extent with a different legal and policy domain; the regulation of human tissues and cells in general. The EGE has also influenced the debate on regulating this domain, to which the discussion now turns.

The EGE and the regulatory and policy frameworks for the use of human tissues and cells in medicine

The European Union has a long-standing body of legislation concerning medicinal products.[91] These are regulated at EU level essentially on the basis of the need to protect consumers within the internal market. However, where medicinal products are derived from human body parts, there are ethical and political objections to conceptualising these

[88] The Nuffield Council on Bioethics is an independent UK body which was established in 1991 by the Nuffield Foundation. It examines ethical issues arising from developments in biology and medicine and is jointly funded by the Nuffield Foundation, the Medical Research Council and the Wellcome Trust.

[89] Following a request by the European Commission on October 18, 2000.

[90] Opinion No.16 para.2.3.

[91] Beginning with Directive 65/65 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products [1965] OJ 22/369. Directive 2001/83 on the Community code relating to medicinal products for human use [2001] OJ L311/67 amends and updates earlier legislation and has itself been amended several times, most recently by Directive 2008/29 amending Directive 2001/83 on the Community code relating to medicinal products for human use [2008] OJ L81/51.

as simple commodities, to be traded within a market.[92] Nevertheless, the European Union has adopted legislation on these products,[93] and on the quality and safety of human tissues and cells when used in medical settings. This legislation includes Directive 2002/98[94] and Directive 2004/23.[95]

In developing its proposals for these Directives, the Commission referred explicitly to the EGE's Opinions,[96] expressly stating that its proposal would reflect these recommendations. The Commission also stated that the EGE's Opinion will be sought and respected in future development of legislation whenever necessary.[97]

The body within the Commission primarily responsible for overseeing EU policy on the use of human tissues and cells in medicine is the EU Health and Consumer Protection Directorate General (DG SANCO). DG SANCO also holds responsibility for the use of organs in transplantation, and blood safety. Article 152 EC is the legal basis for its work, and especially Art.152(4)(a), which states that the European Union,

> "shall contribute to the achievement of the objectives referred to in these articles through adopting:
> (a) Measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures".

For work on tissues and cells more specifically, Directive 2004/23, and the two implementing Directives, are the basis for its actions. Much of DG SANCO's work concerns the "technical" aspects of tissue banking. These include setting basic standards for tissues and cells, so that when they are exchanged across borders, minimum standards, for example of testing for infection and contamination, will apply. Current and future initiatives concern the development of an EU coding system, of EU guidelines for inspection and for quality systems, IT support and a mechanism for the import/export of tissues and cells (outside the EU).[98] We consider below the ways in which the EGE's Opinions have influenced EU policy-making, especially that of DG SANCO, in this field.

[92] This view is expressed in many European codes of ethics, including the Oviedo Convention, and the EGE's Opinion Nos 2, 3, 8 and 11 (all discussed above), and is reflected in the political discussions about the uses of human tissues, notably of Directive 98/44 and Directive 2004/23. On the national political cultures shaping these ethical codes, see "Life: Dignity and Value" in P. Rabinow, *French DNA: Trouble in Purgatory* (Chicago: University of Chicago, 1999), pp.71–111; see also A.M. Farrell, "Is the gift still good? Examining the politics and regulation of blood safety in the European Union" (2006) 14 *Medical Law Review* 155, 174 on the ways in which, "the Blood Directive needs to be read in conjunction with a number of other Directives, which deal with what are more formally described in regulatory terms as 'medicinal products derived from human blood and plasma".

[93] See T.K. Hervey and J.V. McHale, *Health Law in the European Union* (Cambridge: Cambridge University Press, 2004), pp.288–312.

[94] Directive 2002/98 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83 [2003] OJ L33/30.

[95] Directive 2004/23 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [2004] OJ L102/48.

[96] "This proposal for a Directive reflects the recommendations put forth by the EGE": Proposal for a Directive on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells [2002] OJ C227E/505.

[97] Proposal for a Directive on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells [2002] OJ C227E/505 recital 23.

[98] M. Cox and M. Walmar, "The challenges of implementing European regulations on tissues and cells" (2007) R.A.J. Pharma. 443.

(a) Opinion No.2

The GAIEB's early work included Opinion No.2 on products derived from human blood or human plasma. Blood banking was intensely contested in the 1980s and 1990s. Whereas blood services had previously received relatively little public and political scrutiny, the contamination of blood by the HIV/AIDS virus brought the problems, risks and hazards inherent in blood banking to wider public and political attention. Scandals about blood services were unfolding in some European states, where individuals and organisations were prosecuted for their failure to act to protect the recipients of blood after the risks of HIV infection were known.[99] Although blood service officials and health systems in other states emerged relatively unscathed from the crisis, nevertheless, recognition was dawning too of the possibility of vested interests in the supply of blood and products derived from it.

At the time, blood banking per se was outside the scope of Community competence. There was no explicit Treaty basis for formal measures protecting public health. However, blood safety legislation concerning *products* derived from blood could be enacted. Notable amongst these products was plasma, which had been processed and marketed internationally on an industrial scale since the 1970s.[100] Hence the introduction of Directive 89/381.[101] This measure of hard law followed on from intense debates about the risk of specific hazards being transmitted through blood transfusions and products, and the broader issues of vested interests and commercialisation in blood services.

GAEIB Opinion No.2 warrants this Directive as sound.[102] Following its discussion and having regard to the suggestions made by the *Comité Consultatif National d'Éthique pour les Sciences de la Vie et de la Santé* (CCNE, the French bioethics committee), the GAEIB Opinion states that the following ethical principles should be stressed in the Directive: the donee's health, the donor's human dignity, and the non-marketability of the human body.[103]

In the course of its discussion, the GAEIB reviews some criticisms of the Commission's stance, and the language used in EU legislation, which referred to human biological materials as "raw material". Distaste for the implication of this term—that blood was somehow like any other raw product, regulated in terms of markets—had been expressed by the CCNE. This tension between the need to regulate the markets in blood (and, later, tissue and cell) products, and the need to recognise the ethical constraints that militate against the commodification of such products has been an enduring and intractable one. The GAEIB however declares the problem to be one of *terminology*, rather than one of substance.[104]

[99] A. Casteret, *L'affaire du sang* (Paris: La Decouvert, 1992); P. Rabinow, *French DNA: Trouble in Purgatory* (Chicago: University of Chicago Press, 1999); D. Starr, *Blood: An Epic History of Medicine and Commerce* (New York: Alfred A. Knopf, 1998).

[100] Starr, *Blood*, see above fn.99.

[101] Directive 89/381 on the harmonisation of laws relating to medicinal products derived from human blood or plasma [1989] OJ L181/44.

[102] "The Group has scrutinized Directive 89/381/EEC on products derived from human blood and human plasma. It has concluded that it is sound." Opinion No.2 para.3.

[103] Opinion No.2 on products derived from human blood or human plasma (1993) para.3.1.

[104] "Opinion No.28 (blood transfusion), issued on 2 December 1991 by the French National Ethical Committee, considers that the Directive treats blood and plasma as a starting material ... and blood

This Opinion can be viewed in the context of other measures adopted by EU institutions in the 1990s.[105] Given that formal competence for promoting public health had only just been given to the European Union, the setting out of non-binding principles according to which blood donation should be undertaken in the Member States was a primary instrument available at this time. The Opinion shares its approach with that of various soft law measures, for instance on principles of non-commercialisation and voluntary blood donation.[106] Taking this longer view of ethics advice to the European Union on the use of human tissues and cells enables us to consider the dynamics of such advice giving from the outset: the principle that "the human body in general and human blood in particular are not marketable" is a cornerstone of this Opinion. The GAEIB also insists that "nobody should be able to make a profit from a donor's blood".[107] Yet these statements go somewhat against the reality of an industrial blood products industry already in place. Notwithstanding these denials, the question of how to manage the market in products derived from blood or other human tissues and cells, was an emerging area for legislation and public policy in the EU, and one that would expand in scope over the next decade.

(b) Opinion No.11

The work of the EGE proper on the uses of human biological materials begins with Opinion No.11 on ethical aspects of human tissue banking (1998). The EGE defines the scope of this Opinion as including tissues and cells of human origin, including stem cells from umbilical cord blood, but excluding blood and human organs for transplant. In its preamble, the Opinion refers to a range of measures, beginning with the EC Treaty, including specific directives on the use of blood products[108]; data protection[109]; a resolution of the European Parliament on prohibiting trade in transplant organs[110]; and the recommendations of the Council of Europe on Human Tissue Banks,[111] and the Council of Europe Convention on Human Rights and Biomedicine (Oviedo Convention) 1997.

derivatives as medical products, this making them seem to be tradable goods, contrary to the principle that the human body is not marketable and contrary to human dignity. The Commission does not accept this. Since 1965 the Community definition of medicinal products given in article 1 of Directive 65/65/EEC has applied to blood products ... The problem is thus purely terminological." (Opinion No.2 para.1.3.)

[105] See, for instance, Communication on blood self-sufficiency in the European Community COM(93) 198 final; Conclusions on self sufficiency in blood in the European Community [1994] OJ C15/6; Communication on blood safety and self-sufficiency in the European Community COM(94) 652 final; Resolution on blood safety and self sufficiency in the Community [1995] OJ C164/1; Resolution on strategy towards blood safety and self sufficiency in the European Community [1996] OJ C374/1; and Recommendation 98/463 on the suitability of blood and plasma donors and the screening of donated blood in the European Community [1998] OJ L203/14.

[106] *Report on the promotion by Member States of voluntary unpaid blood donations* COM(2006) 217; Recommendation 98/463.

[107] Opinion No.2 para.2.3.

[108] Directive 89/381 on the harmonisation of laws relating to medicinal products derived from human blood or plasma [1989] OJ L181/44; The EC Treaty as amended, and in particular Art.152, para.4(a) referring to substances of human origin; Opinion No.11, Preamble.

[109] Directive 95/46 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1995] OJ L281/31.

[110] Resolution A3-0074/93 on prohibiting trade in transplant organs [1993] OJ C268/26.

[111] Council of Europe Committee of Ministers, Recommendation R (94)1 of the Committee of Ministers to Member States on Human Tissue Banks, adopted March 14, 1994.

The EGE identifies an "urgent need to regulate the conditions under which human tissues circulate within the European market",[112] and proposes that "the establishment of a European structure for the protection of health should also be envisaged".[113] The Opinion thus foreshadows some of the health and safety issues that would eventually be addressed through legislation, and sets out an agenda for some of the ethical criteria to be considered. It refers to the ethical imperative to protect health in accordance with current understandings of best practice[114]; the integrity of the human body[115]; the need to obtain "prior, informed, and free consent of the person concerned" before procurement of human tissues[116]; and stresses the imperative to protect donors' identities.[117] It also addresses preventing discrimination through the revealing of personal information,[118] and encouraging altruistic donation in Member States.[119] Further, the EGE argues that "safety rules must be uniform throughout the European Union",[120] and:

> "In principle, tissue bank activities should be reserved to public health institutions or non profit organisations ... this means that the delivery price of the tissues only covers the bank's expenses relating to the tissues in question."[121]

The EGE urges public investment in tissue banking. It advocates equity in accessing therapeutic opportunities presented by the use of human tissues.[122] Tissue imports or exports to/from outside the European Union "should be licensed by public authorities".[123] In conclusion, the EGE recommends a regular review of policies in the Member States,

> "to obtain and diffuse data on practices relating to human tissues, from procurement to distribution, the organisation of tissue banks, particularly concerning the profit-making or non-profit making aspect and the true dimension of imports and import controls".[124]

In summary, this Opinion not only declares key ethical principles, but sets out a wide-ranging agenda for policy and legislation to regulate the uses of human tissues. Many of these issues would be taken up by EU institutions in subsequent discussions about and proposals for legislation to regulate the uses of human tissues and cells. However, empirical scrutiny of the industry shows that there is a naiveté about the insistence on not profiting from human tissues. For instance, processing fees effectively fund a range of public and private bodies, which gain income from a market in these valued human

[112] Opinion No.11 para.2.
[113] Opinion No.11 para.2.1.
[114] "Tissues, in particular those intended for transplantation to third parties or for the preparation of pharmaceutical specialties, must undergo advance testing to provide maximum health guarantees in accordance with the 'state of the art'." (Opinion No.11 para.2.1.)
[115] Which "should be ensured when procuring tissues from an individual, whether living or dead": Opinion No.11 para.2.2.
[116] Opinion No.11 para.2.3.
[117] Opinion No.11 para.2.4.
[118] Opinion No.11 para.2.5.
[119] Opinion No.11 para.2.6.
[120] Opinion No.11 para.2.7.
[121] Opinion No.11 para.2.8.
[122] Opinion No.11 para.2.9.
[123] Opinion No.11 para.2.10.
[124] Opinion No.11 para.2.11.

tissues.[125] Farrell argues that, in the case of earlier policy making, on blood safety, the insistence of EU institutions on using a language of altruism obviated recognition of the commercial blood processing sector.[126] This then delayed the regulation of the sector. Our analysis of the EGE's work on tissue banking points to a similar dynamic: the EGE avoids recognising the extent of the commercial sector in tissue and cell processing and banking.

How did the EGE's Opinions affect EU law and policy? In terms of legislative proposals, the eventual proposal for a Directive on the setting of standards of quality and safety for the donation, procurement, storage and distribution of human tissues and cells[127] reflects and endorses many of the EGE's recommendations (including those summarised above). It cites Opinion No.11, and expressly states that it "reflects the recommendations put forth by the EGE",[128] whose Opinions will be sought in the future wherever necessary.

The Commission press release announcing its proposal also notes that the Opinions of the EGE, the EU Charter of Fundamental Rights, and documents of the Council of Europe were taken into consideration.[129] Here, the EGE is placed on a level with much longer-standing and more authoritative bodies, both within the European Union, and beyond. Its Opinions are also placed on a level with the European Union's major human rights instrument. This thus underscores the EGE's authority as a body that discerns and disseminates ethical principles within Europe.

The final text of the Directive, especially its preamble, explicitly features ethical principles found in the EGE Opinion.[130] After more than a decade of interaction between the GAEIB/EGE and EU soft law measures, the EGE's Opinions on human tissues and cells found their way into EU law.

Some proposed ethical provisions were however ultimately not accepted. These fall outside the scope of Art.152 EC.[131] The EGE's influence on legislative proposals is constrained by the need to express EU law as consistent with the empowering legal basis provisions of the Treaty, none of which gives the EU competence to adopt laws on ethical principles per se. This can have the effect of strengthening the technical regulatory aspects

[125] B. Parry, "Entangled exchange: Reconceptualising the characterisation and practice of bodily commodification" (2008) 39 *Geoforum* 1133.

[126] See Farrell, "Is the gift still good?" (2006) 14 *Medical Law Review* 155, 174 .

[127] Proposal for a Directive on the setting of standards of quality and safety for the donation, procurement, storage and distribution of human tissues and cells [2002] OJ C227E/505.

[128] See Proposal for a Directive on the setting of standards of quality [2002] OJ C227E/505.

[129] Press Release IP/02/894 available at *http://europa.eu/rapid/pressReleasesAction.do?reference=IP/02/894&format=HTML&aged=0&lg=lt&guiLanguage=en* [Accessed October 1, 2008].

[130] For instance, "tissue and cell application programmes should be founded on the philosophy of voluntary and unpaid donation . . . altruism of the donor, and solidarity between donor and recipient": Directive 2004/23 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [2004] OJ L102/48 recital 18.

[131] Commission Amended Proposal for a Directive on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells, COM(2003) 340 final, p.3; European Parliament legislative resolution on the proposal for a Directive on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells COM(2002) 319, Amendment 9 relating to the processing of stem cells, Amendment 14 relating to creating a code of conduct to protect human dignity, Amendment 48 on the protection of people not in a position to give their free and informed consent and the creation of an ethics commission which would lay down criteria for cell and tissue retrieval.

of Directives, and correspondingly, reducing the influence of the EGE. This tendency is seen even more starkly in the two subsequent implementing Directives,[132] which focus on technical requirements for donation and for coding, processing, preservation, storage and distribution, and contain very little reference to ethics.

To what extent have the EGE's Opinions on the use of human tissues and cells in medicine influenced EU policy, as distinct from law? Although much of DG SANCO's policy work concerns the technical aspects of human tissue banking, DG SANCO's work also addresses remuneration for both blood and tissue/cell donation, which, as we have seen, are long standing ethical touchstones for blood and tissue banking in Europe. Questions about remuneration for donation have been raised in questionnaires to Member States, and the Commission intends to continue to review Member States' policy and practice in this field. In its sections on priorities, the lead official for this work, Eduardo Fernandez Zinke, states that:

> "Specific questions related to blood, tissues, cells and organs remain on the *promotion of voluntary unpaid donations*, inspections, electronic exchange of data, and optimal use ... Stem cells, reproductive cells, and new human derivatives are special cases that will require specific attention."[133]

Given that various forms of compensation are offered in Member States to tissue donors, policy on "voluntariness" is not entirely resolved and is the subject of ongoing monitoring and promotion by DG SANCO. Thus, the normative issues with which the EGE has been concerned, namely the stress on altruism in tissue donation and solidarity in tissue banking, continue to be the subject of some policy work by the Commission. These ongoing efforts continue despite official pronouncements to the effect that ethical issues fall within the jurisdiction of Member States.

Thus the influence of EGE Opinions on Commission policy takes place within ongoing dialogues about the tensions between commercialisation and developing European enterprise on the one hand and values of solidarity and altruism on the other. Again the EGE plays a brokering role. It apparently adopts a strong "ethical" stance concerning the European approach to blood, organ and tissue donation, while the bases for the European Union's involvement—both the regulation for the EU "market" in human tissues and cells and the protection of public health within the European Union—leave significant leeway to national authorities. Here the influence of the EGE appears to be more indirect, and perhaps more significant at policy making level. To explore this proposition further, we turn now to another EGE Opinion, concerning ethical aspects of umbilical cord blood banking.

[132] Directive 2006/17 implementing Directive 2004/23 as regards certain technical requirements for the donation, procurement and testing of human tissues and cells [2006] OJ L38/40 and Directive 2006/86 implementing Directive 2004/23 as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells [2006] OJ L294/32 respectively.

[133] Presentation by Eduardo Fernandez Zinke to the Human Tissue Authority, "An Overview of the European Tissues and Cells Directives—a European Commission Perspective" (emphasis added), available at *http://www.hta.gov.uk/search.cfm?FaArea1=CustomWidgets.content_view_1&cit_id=401&useCache=false* [Accessed October 1, 2008].

(c) Opinion No.19

Health services have collected donated human umbilical cord blood since the early 1990s, to make haematopoietic stem cells from this source available for use in transplant medicine. These cells are used to treat a range of malignant, metabolic, and blood forming diseases: approximately 8,000 transplants have been undertaken using these cells, which provide an alternative to bone marrow transplants, for children and, more recently, for adults.[134] A number of "cord blood banks" have been established for these purposes within European public health services.[135]

An emerging ethical controversy about commercial activity in cord blood banking was brought to wider attention in early 2001, when a private cord blood bank was established in Europe by the US-based company, Cryo-Cell. During a European Parliamentary session in April that year, a Dutch MEP, Ria Oomen-Ruijten, questioned the legitimacy of Cryo-Cell's direct-to-parents advertising methods and the therapeutic claims it used to market its services, suggesting it was a matter for the EGE to consider.[136] She labelled it a "campaign [that] plays on the concern of prospective parents to prevent illness, and the fear of death". The questions echoed broader concerns about consumer protection and public health raised in the debates on the Biotechnology Directive.[137] A longer running problem associated with commercial cord blood banking was the patent[138] granted by the European Patent Office (EPO), to a private company, Bioctye, for techniques of cryo-preserving cord blood stem cells. This had generated an alliance of clinicians, tissue bankers, and others, who lobbied for the interests of the emergent public tissue bank sector. They argued that the consequence of allowing a patent for this widely used technique would be that the costs of licenses would ultimately undermine treatment of patients needing transplants.[139] Although, as we have seen, Biocyte's patent was eventually revoked by the EPO, the case had focussed interest and resulted in the building of alliances of key professionals, who were then able to raise the profile of concerns about commercial cord blood banking. The Commission's initial response to Mrs Oomen-Ruijten's question about commercial cord banking emphasises the constraints on its power to intervene in these commercial enterprises, where they are allowed by Member States:

[134] C.G. Brunstein, D.C. Setubal and J.E. Wagner, "Expanding the role of umbilical cord blood transplantation" (2007) 137(1) Br.J. Haematol. 20.

[135] Initially in specialist centres in Paris, Milan, and Dusseldorf, and now more extensively, throughout Europe.

[136] Parliamentary Written Question E-1079/01 by Ria Oomen-Ruijten (PPE-DE) to the Commission, April 6, 2001, subject "Commercial action for the storage of umbilical cord blood for obtaining stem cells" [2001] OJ C340E/166.

[137] Directive 98/44.

[138] Granted first in the US: US PAT. 5004681, WL 1991 949051 (US PTO Utility), title: "Preservation of fetal and neonatal hemotopoietic stem and progenitor cells of the blood" (issued April 2, 1991). US PAT 5192553, 1993 WL 1136900 (US PTO Utility), title: "Isolation and Preservation of fetal and neonatal hemotopoietic stem and progenitor cells of the blood and methods of therapeutic use" (issued March 9, 1993).

[139] J. Wise, "Doctors fight US company patent on umbilical cord blood" (1997) 314 B.M.J. 1145.

> "The Commission has no information on the existence of comparable commercial organisations in the Community. No Community legislation currently exists on this type of service. It falls to Member states to deal with the problem."[140]

After being prompted by Mrs Oomen-Ruijten, who reiterated her concerns and requested that the matter be referred for consideration by the EGE, the Commission sought the EGE's Opinion in August 2001.[141]

The formulation of the problem to be considered—commercial cord blood banking—is unusually specific, but it falls within the EGE's broader work on human tissues and cells. The EGE's Opinion No.19 on ethical aspects of umbilical cord blood banking states that,

> "the legitimacy of commercial cord banks for autologous use should be questioned as they sell a service which has, presently, no real use regarding therapeutic options. Thus they promise more than they can deliver ... [and] the activities of such banks raise serious ethical criticisms".[142]

Despite this view, and the recorded wish of some members of the EGE that this activity should be prohibited, the principles of freedom of enterprise and of consumer choice weigh heavily.[143] The EGE considers the implications of commercial cord blood banks trading in those Member States that permit their establishment, and providing services to parents in other Member States. The Opinion recommends strict regulation of both public and private banks (where allowed) by the competent national authority.[144] Appropriate information must be provided to consumers.[145] The EGE also welcomes Directive 2004/23[146] which sets an overarching EU legal framework encompassing both public and commercial cord blood banks.[147] The possibility of bankruptcy of commercial cord banks is considered. The Opinion recommends that arrangements for the continuity (of cell banking) or for indemnity (for loss of such services) should be in place.[148] Collection of cord blood must not detract from care during childbirth.[149]

To facilitate fair and widespread access to cord blood transplantation, the Opinion encourages use of public cord blood banks for individuals or families at risk of specific diseases.[150] Cells should be banked from "an increasing multiethnic population to cater for all [tissue] types, regardless of their ethnic origin".[151] To make this viable, the EGE

[140] Answer to Written Question E-1079/01 by Ria Oomen-Ruijten given by Mr Prodi on behalf of the Commission on May 8, 2001 [2001] OJ C340E/167.

[141] Written question by Ria Oomen-Ruitjen to the Commission on June 26, 2001, and answer given by Mr Prodi on behalf of the Commission September 6, 2001 [2001] OJ C81E/67–68.

[142] Opinion No.19 para.2.1.

[143] "A strict ban would represent an undue restriction on the freedom of enterprise and the choice of individual couples": Opinion No.19 para.2.2.

[144] Opinion No.19 para.2.3.

[145] Opinion No.19 paras.2.4 and 2.5: "Any kind of advertising made by commercial cord banks in the media, including on the Internet, must be adequately controlled by public authorities."

[146] Directive 2004/23 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [2004] OJ L102/48; see Opinion No.19 para.2.6.

[147] Opinion No.19 para.2.6.

[148] Opinion No.19 para.2.7.

[149] Opinion No.19 para.2.8.

[150] Opinion No.19 para.2.9.

[151] Opinion No.19 para.2.10.

recommends increased funding for both public cord blood banks and the networks and registries that co-ordinate their activities.[152] The Opinion concludes by recommending that a,

> "European debate on the increasing role of the market in the healthcare system and its advantages and disadvantages should allow European citizens to be aware of the present trends and their implications, in particular on the issues raised in the present Opinion".[153]

As with earlier pronouncements on tissue banking, in this Opinion, the EGE is mediating between values of commerce and enterprise; and of altruism and solidarity. The Opinion recognises, but fails to confront, the threat posed by commercial bodies. It resorts to the suggestion of better information and a public debate to diffuse concern.[154]

The timing and scope of Opinion No.19 suggests the EGE's consideration of it (between late 2002 and March 2004) overlaps substantially with the discussion by other EU institutions of proposals for the Directive 2004/23 on the safety of human tissues and cells.[155] The process of considering and issuing the new Opinion on cord blood banking appears to have given the EGE the opportunity to reiterate principles that feature in its earlier work, and to update the context of its declarations. Examples of concerns that were considered first in Opinion No.11, then reiterated in Opinion No.19, include the imperative to support public sector tissue banking, to constrain the activities of commercial organisations in this domain; and to continue to develop regulations to protect consumer safety, within a public health framework. The tension between the values of freedom of enterprise/freedom of consumer choice, and those of solidarity in tissue banking is made more explicit in the later Opinion. The Opinion also reiterates the freedom of Member States to decide on normative questions inherent in tissue banking.

What influence can we discern for EGE Opinion No.19, in measures of EU law? The picture is less straightforward than with the other Opinions on the uses of human tissues discussed in this section. Beginning with "hard law", we have not found evidence of this Opinion in legislative proposals. It may be that the tight focus of this Opinion—concerned exclusively with one form of tissue banking—explains this absence of citations in legislative proposals, which are more likely to address a sector than a particular activity within it. Nor have we found specific evidence of Opinion No.19 having been used in the interpretation of hard law, to date.

The question of commercial cord banking, strictly speaking, remained one for Member States and their national laws. Thus, such activity continued to be prohibited in some

[152] Opinion No.19 para.2.12.

[153] Opinion No.19 para.2.13.

[154] "If commercial cord blood banks are allowed, appropriate information should be given to the consumers willing to use their services, including the fact that the likelihood that the sample may be used to treat one's child is currently negligible, that the future therapeutic possibilities are of a very hypothetical nature and that up until now there is no indication that the present research will lead to specific therapeutic applications of one's own cord blood cells." (Opinion No.19 para.2.4.) "A wide European debate on the increasing role of the market in the healthcare system and its advantages and disadvantages should allow European citizens to be aware of the present trends and their implications, in particular on the issues raised in the present opinion." (Opinion No.19 para.2.13.) The emphasis on provision of information to consumers as a solution to these policy problems was also evident in our interviews with Göran Hermerén on June 20, 2007 and Pere Puidomenèch Rosell on June 20, 2007.

[155] The Directive was adopted March 2004, just two weeks before the EGE's Opinion No.19 was issued.

Member States, for example in France, and allowed in others, for example in the United Kingdom. It may be that Opinion No.19 has some influence on the implementation by each Member State's competent authority for the regulatory framework set out in Directive 2004/23. Meanwhile, the Commission has explicitly monitored the extent of the private cord blood bank sector, and the legal position regarding this in each Member State.[156] This may well prove to be a prelude to further measures, perhaps in the form of setting of technical standards, which effectively make commercial cord banking so expensive that it is not viable to undertake in the European Union.

Although not demonstrably influential in EU law or formal policy, Opinion No.19 appears to have been taken up actively in wider national networks of professionals, ethicists, and public sector tissue banks. For example, the Opinion has been cited by national bioethics and professional bodies, who have in turn issued their own position statements on cord blood stem cell banking.[157] All these declarations serve to question the legitimacy of private cord banking. Support of public cord banking, through funding to co-ordinating bodies, alongside more intense scrutiny of private cord blood banks, may have the eventual effect of discouraging private firms from starting up or continuing in this particular market.

Overall, it may be premature to say more than that, at present, the influence for this Opinion appears to have been primarily through national bioethics bodies, professional/clinical networks (national and transnational), and national competent authorities under the Directive. To this extent, it is somewhat exceptional amongst the Opinions discussed above. Nevertheless, adopting a broader analysis of the EGE's influence, that includes the sphere of formal making and interpreting of law, but goes beyond this to consider the EGE's part in wider networks of regulatory structures, Opinion No.19 can be said to be influential.

In its early opinions, the GAEIB was one of the bodies steering a course through a review of EU policies on blood banking, anticipating problems that could not (yet) be addressed through hard law. At the same time, Opinion No.2 reframed an ethical and political controversy: is it acceptable to describe donated human blood as "raw material"? Blood banking was an intensely contested field in the early 1990s, yet the declaration reclassifies the contested ethics and politics of blood banking, as a technical matter. Reclassification of ethical and political matters as technical problems was to offer a successful route for managing some of these controversies.[158] Anticipating and setting out formative frameworks for subsequent law and policy, and diffusing political tensions, appear in this case to be the key elements of the GAEIB's influence.

[156] EC Health and Consumer Protectorate Directorate-General, "Summary Table of Responses from Competent Authorities: Questionnaire on the transposition and implementation of the European Tissues and Cells regulatory framework" (February 6, 2007) SANCO C6 CT/gcs D 360045, s.9 "Private autologous cord blood banking", pp.49–52.

[157] For instance, the UK's Royal College of Obstetricians and Gynaecologists Scientific Advisory Committee Opinion Paper 2, "Umbilical Cord Blood Banking" (Revised June 2006); Royal College of Midwives Guidance Paper 1a, "Commercial umbilical cord blood collection" (2002) *5,12 RCM Journal* 422, 422–424; the Swedish National Council on Medical Ethics (Statens medicinsk-etiska råd (SMER)) Opinion concerning umbilical cord blood banking (June 23, 2005); and the Belgian Advisory Committee on Bioethics Opinion No.42 of April 16, 2007 on "Umbilical Cord Blood Banks".

[158] A.M. Farrell, "Governing the Body: Examining EU Regulatory Developments in Relation to Substances of Human Origin" (2005) 27 *Journal of Social Welfare and Family Law* 427, 435.

Turning to the EGE's work, we have seen that subsequent EU legislation embeds many of the suggestions contained in the EGE's Opinion No.11. Further, this Opinion is referred to throughout the legislative proposals for Directive 2004/23 and related discussions about the regulation of tissue and cell banking. Given the number of times, and the ways, in which it is cited in key discussions about the legislation, the EGE appears to be emerging into a recognised authority in the complex fields of intersection between technologies, donors and their donated biological materials, and patients.

In contrast, for EGE Opinion No.19, we found no evidence of the EGE's recommendations being cited in EU legislative proposals. In this case however, the broader influence of the EGE's Opinion is quite substantial. It has been widely cited by national bioethics bodies, professional groups, networks, and (EU) inspection bodies. In this sense, it may also have provided an interpretative reference point for the conduct of individuals—for instance, clinicians, parents, commercial bodies. This Opinion also appears to be reflected in policy at an operational level; see, for instance, the explicit monitoring of private cord banking by DG SANCO.

Taking together these three areas concerning regulation of human tissue in medical settings, the EGE's influences work in a range of ways. Indeed, its very flexibility in confronting policy dilemmas at different stages is part of its power within the network of institutions of the European Union and its Member States. The EGE's work is part of the necessary creation of boundaries and categories in the complex fields of responsibility, power, and ethics in the life sciences, as described by Jasanoff.[159] Amongst the politically significant boundaries with which the EGE is working are the following: how and when is human biological material permitted to be a commodity; where should provision be through private markets as opposed to solidarity-based, altruistic public structures; and what is defined as being in the scope of public health as an EU-level concern? These boundaries must be managed within the tension between promoting free trade and economic competitiveness and realising other political values and principles in the European Union. The EGE's mandates explicitly state its intended contribution towards "establishing common rules to enable the internal market to operate in accordance with Europe's ethical values".[160] Given the constraints on the Commission, which must leave explicitly ethical issues for Member States, the reiteration and advocacy of ethical principles is a core function of the EGE. In addition, the EGE has also been adept at mutating such principles, or reworking their application, where it recognises that freedom of enterprise or consumer choice are visibly under threat.

[159] "A major function of policy making for the life sciences is to create and maintain boundaries that correspond to people's pre existing ethical and social sensibilities concerning the products of biotechnology ... Indeed, perhaps the most influential form of boundary work in contemporary societies is done by legal institutions as they try to sort out the infinite variety of human actions and their consequences into finite and pragmatic conceptual categories ... But politically significant boundary work also takes place in a multitude of more specialized forums that are less transparently in the business of boundary maintenance than legislatures or the courts, such as expert advisory committees, parliamentary commissions, ethics review boards, and nongovernmental organizations." S. Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton: Princeton University Press, 2005), pp.26–27.

[160] See EGE website, Mandate 1998–2000, Introduction at *http://ec.europa.eu/european_group_ethics/archive/1998_2000/intro_en.htm* [Accessed October 1, 2008].

The EGE's role in research involving human embryonic stem cells

Our final example concerns the EGE's influence in refining the ethical issues at stake and the limits and conditions for stem cell research, in particular human embryonic stem cell research, under successive EU-funded "Framework Programmes" for research and their processes of ethical review. We begin with the Fifth Framework Programme (FP5), which ran from 1998–2002, and the process of adopting its enabling legislation.[161]

(a) Opinion Nos 12 and 15

In 1998, the European Commission asked the EGE for its Opinion on a European Parliament amendment proposing to exclude from EU funding research projects that "result in the destruction of human embryos", in the context of adopting legislation for FP5.[162] Opinion No.12 on the ethical aspects of research involving the use of human embryos in the context on the Fifth Framework Programme dismisses as "artificial" any distinction between research that results in the destruction of a human embryo and research that enables an embryo to develop to full term, stating that the implantation into a woman's uterus of an embryo that has been the subject of research would be an "unacceptable risk".[163] While the EGE accepts the amendment to prohibit EU-level funding for research that results in the destruction of human embryos, it argues that, in order to respect different philosophical, moral or legal approaches and diverse national cultures, funding under the FP5 should not a priori exclude human embryo research in Member States where it meets national regulatory and ethical requirements.[164]

During the lead up to the Sixth Framework Programme (FP6),[165] the EGE adopted another opinion on the subject: Opinion No.15 on the ethical aspects of human stem cell research and use.[166] The Opinion "reviews the ethical issues raised by stem cell research and use", in the general context of EU research policy.[167] The basis of its review is a continuum of types of human embryo[168] and types of stem cells,[169] as well as a distinction between "supernumerary" embryos and those created for research.[170] This continuum allows the EGE to suggest that some research projects involving human stem cells are more ethically acceptable than others.[171]

Concerning the ethical acceptability of human embryonic stem cell research in FP6, the EGE again finds no argument for excluding from funding human embryonic research

[161] Decision 182/1999 concerning the Fifth Framework Programme of the European Community for research, technological development and demonstration activities (1998 to 2002) [1999] OJ L26/1.
[162] Opinion No.12, p.1.
[163] Opinion No.12 para.2.7.
[164] Opinion No.12 para.2.8.
[165] Decision 1513/2002 concerning the Sixth Framework Programme of the European Community for research, technological development and demonstration activities, contributing to the creation of the European Research Area and to innovation (2002 to 2006) [2002] OJ L232/1.
[166] Opinion No.15.
[167] Opinion No.15 para.2.1.
[168] Opinion No.15 para.1.5, which distinguishes between the embryo at two to three days, four to five days, and five to seven days.
[169] Including adult stem cells, cord blood stem cells, stem cells drawn from foetal tissue, and drawn from embryonic blastocysts: see Opinion No.15 paras.1.7, 1.8, 2.4.
[170] Opinion No.15 para.1.12.
[171] B. Salter and M. Jones, "Biobanks and bioethics: the politics of legitimation" (2005) 12(4) J.E.P.P. 16.

for therapeutic purposes, where Member States allow this type of research and where it complies with the other ethical and legal requirements of the Framework Programme.[172] However the EGE goes a little further than in Opinion No.12, by stating that,

> "the creation of embryos for the sole purpose of research raises serious concerns since it represents a further step in the instrumentalisation of human life".[173]

The EGE also recommends that conditions are placed on the source from which embryos are derived:

> "The creation of embryos with gametes donated for the purpose of stem cell procurement [is] *ethically unacceptable*, when spare embryos represent a ready alternative source",

while "the creation of embryos by somatic cell nuclear transfer for research on stem cell therapy would be *premature*" as alternative sources of supernumerary stem cells exist (our emphasis).[174] The EGE suggests that FP6 should provide funding for stem cell research based on alternative (to created embryos) sources, subject to establishing appropriate procedures and means for ethical assessment. The Opinion shows a preference for research using adult stem cells, by arguing that funding should be devoted to exploring their differentiation potential.[175]

(b) Opinion No.22

On November 22, 2006, Commission President Barroso asked the EGE for an Opinion on implementing measures for ethics review of research projects on human embryonic stem cells. This was to "assure that the ethical rules and requirements are fully met".[176] Before detailing its implementation measures in Opinion No.22, the EGE acknowledges the political decision taken as the starting point for its Recommendations, but emphasises that,

> "the ethical dilemma regarding the moral status of the human embryo and its use in research still persists. The EGE therefore stresses that the ethical differences of opinion concerning human embryonic stem cell research have not been resolved".[177]

In its Opinion, the EGE recommends that applicants must provide information that the human embryonic stem cells to be used result from non-implanted IVF embryos[178] and,

> "if alternatives to human embryonic stem cells with the same scientific potential as embryo-derived stem cells will be found in the future, their use should be maximised".[179]

[172] Opinion No.15 para.2.5.
[173] Opinion No.15 para.2.7.
[174] Opinion No.15 para.2.7.
[175] Opinion No.15 para.2.8. "Differentiation potential" is a way in which different types of stem cells can be distinguished as it refers to the ability of different types of stem cells to reconstitute one or several types of tissue.
[176] Letter sent by President Barroso to the EGE on November 22, 2006.
[177] Opinion No.22 para.IV.1.
[178] Opinion No.22 para.IV.2.2.
[179] Opinion No.22 para.IV.2.3.1.

The EGE perceives rights of donors as paramount and recommends that funding applicants should be able to confirm that no pressure has been put on donors at any stage; that the donor's health has not been put at risk by excessive ovarian stimulation; that donors are aware that consent can be withdrawn up to the stage of stem cell creation; and that no financial incentives are offered to donate embryos for research.[180] Ideally, human embryonic stem cell lines banked in the new European stem cell registry should be used.[181]

In addition to the ethical review, the EGE recommends that project proposals related to human embryonic stem cells undergo a scientific review. The EGE states that the scientific review should address issues such as whether the research objectives could be achieved with alternatives to human embryonic stem cells and whether the applicants can demonstrate that their research is aimed at improving human health or boosting biomedical knowledge.[182] Furthermore, the scientific panel should,

> "ensure that researchers of human embryonic stem cell FP7 projects collaborate nationally and internationally in order to minimise the use of human embryonic stem cells within FP7 funded projects and to achieve complementary synergy rather than competition".[183]

Here ethical advice is being used to bolster the synergies, and hence at least potentially the global competitiveness, of European biotechnological research.

Finally, the Group addresses the wider ethical aspects of research using human embryonic stem cells. As the ethical conflicts concerning these cells have not been resolved either academically or politically, the EGE recommends that, under FP7,

> "funding should be provided in order to foster further collaborative and multidisciplinary international research on the ethical implications of human embryonic stem cell research and the pertinent surrounding issues, as well as to encourage informed public debate".[184]

Researchers who receive funding for human embryonic stem cell research under FP7 should also be encouraged to engage with social, political and ethical debates.[185]

Under FP5, EU-funded research was required to take account of the European Council Declaration at Amsterdam and the European Parliament resolution on the banning of human cloning and of relevant EU legislation.[186] Opinions of competent authorities, in particular the EGE, were also to be taken into account, although Opinion No.12 was not specifically mentioned. Accordingly,

> "research activity which modifies or is intended to modify the genetic heritage of human beings by alteration of germ cells or by acting at any other stage in embryonic development and which can make such alteration heritable",

[180] Opinion No.22 para.IV.2.3.2.
[181] Opinion No.22 para.IV.2.4.
[182] Opinion No.22 para.IV.2.1.
[183] Opinion No.22 para.IV.2.1.
[184] Opinion No.22 para.IV.3.
[185] Opinion No.22 para.IV.2.4.
[186] Decision 182/1999.

was prohibited.[187] Likewise,

> "research activity, understood in the sense of the term 'cloning', conducted with the aim of replacing a germ or embryo cell nucleus with that of the cell of any individual, a cell from an embryo or a cell coming from a late stage of development to the human embryo",[188]

would also not be supported.

Salter and Jones[189] claim that the EGE had become a political broker, as its Opinion had undoubtedly influenced the FP5 research agenda to exclude any research activity that involved cloning or germ-cell alteration. In the view of Salter and Jones,[190] ethics is a suitable and legitimate tool for political bargaining to reconcile the scientific demands for human embryo research with the cultural opposition of certain Member States. The President of the Commission assigned the EGE this political bargaining role when he requested its Opinion on the ethical aspects of research involving the use of human embryos in the context of FP5. Thus we can detect the beginnings of a shift in the regulation of science funding and research from a purely technocratic preserve to one where socio-cultural considerations are also deemed necessary.

The debate to set the agenda for FP6[191] and its priority of genomics and biotechnology in health occurred during a period of intense political activity in Europe in response to the sensitive ethical and legal issues raised by new genetic technologies. At the core of the political attention was the varied ethical and legal status afforded to the human embryo by the individual Member States. Some Member States even considered opposing the adoption of FP6 because of this issue, while the European Parliament voiced its concern that it had not been thoroughly consulted on bioethics.[192] Thus the European Union's inability to reconcile through legislation the conflicting national positions attracted intense political and public scrutiny.

When, in June 2000, the UK Department of Health's report, "Stem cell research: medical progress with responsibility",[193] argued that human embryo research for therapeutic purposes (including somatic cell nuclear transfer) should be permitted, the EU national cultural positions on embryonic stem cell research were thrown into sharp relief.[194] In

[187] Decision 182/1999 [1999] OJ L26/1, 13.

[188] Decision 182/1999 [1999] OJ L26/1, 13.

[189] B. Salter and M. Jones, "Human genetic technologies, European governance and the politics of bioethics" (2002) 3(10) *Nature Reviews Genetics* 808.

[190] B. Salter and M. Jones, "Biobanks and bioethics: the politics of legitimation" (2005) 12(4) J.E.P.P. 710.

[191] Decision 1513/2002.

[192] *Green Light For Sixth Framework Programme* (October 2, 2002), Record Control number (RCN) 19019, which specifies Italy, Germany and Ireland as having conflicts with national legislation, available at *http://cordis.europa.eu/search/index.cfm?fuseaction=news.document&N_LANG=EN&N_RCN=19019&q=DD8EBAC119EA3902EC9EF4EA3E80A6DB&type=sim* [Accessed October 1, 2008].

[193] Department of Health, "Stem cell research: medical progress with responsibility. A report from the Chief Medical Officer's expert group reviewing the potential of developments in stem cell research and cell nuclear replacement to benefit human health" (June 2000) available at *http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/*@dh/@en/documents/digitalasset/dh_4065085.pdf [Accessed October 1, 2008].

[194] In 2001, the UK's Human Fertilisation and Embryo (HFEA) Act (Research purposes) further fuelled the debate by allowing embryos to be created for research purposes and also allowing research on therapeutic cloning—whereby such embryos may only be kept for up to 14 days.

response, the European Parliament passed a resolution opposing both reproductive and therapeutic cloning which was seen as "irreversibly crossing a boundary in research norms" and as contrary to public policy as adopted by the European Union.[195] The subsequent European debate became focussed on agreeing a set of ethical principles that did not conflict with differing cultural conceptions of the ethical and legal status of the human embryo. The EGE, on its own initiative, made a significant contribution to that debate with Opinion No.15.

The amendments made to the proposals for FP6 during its first and second readings in Parliament in late 2001 and early 2002 reflect a particular concern with the "ethical issues at stake".[196] Thus the Decision of September 30, 2002 adopting a specific programme for research meant that FP6 would not fund research activity "aiming at human cloning for reproductive purposes" or "intended to modify the genetic heritage of human beings which could make such changes heritable" or,

> "intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer".[197]

Nor would the Commission fund, pending the establishment of detailed implementing provisions by the end of 2003, research projects involving the use of human embryos and human embryonic stem cells with the exception of projects involving banked or isolated human embryonic stem cells in culture. In the interim, the Commission prepared a report to present to the European Parliament and Council that monitored scientific advances and needs, and the evolution of international and national legislation, regulations and ethical rules, taking into account the Opinions of the GAEIB/EGE.[198] The report, published in early April 2003, also formed the basis for discussion at an inter-institutional seminar on bioethics held later that month that aimed to contribute to a Europe-wide discussion on the ethical issues of biotechnology, particularly on human embryonic stem cells, in order to enhance public understanding.[199] Taking into account the seminar's outcome, the Commission submitted a proposal[200] establishing further guidelines on principles for deciding on the EU funding of research projects using human embryos and human embryonic stem cells.

In accordance with the Commission proposal, the Council adopted a decision to amend Annex I to the Council Decision of September 30, 2002 to reflect that,

[195] Resolution on human cloning PE T5-0375/2000 [2001] OJ C135/263.

[196] Addendum to Draft Minutes 2451st meeting of the Council of the European Union (Competitiveness) (Internal Market, Industry and Research) held in Brussels on September 30, 2002, 12523/02. ADD 1 REV 1, Annex F to Commission Staff Working Paper, *Report on Human Embryonic Stem Cell Research* SEC(2003) 441.

[197] Decision 2002/835 adopting a specific programme for research, technological development and demonstration: "structuring the European Research Area" (2002–2006) [2002] OJ L294/44.

[198] Commission Staff Working Paper, *Report on Human Embryonic Stem Cell Research* SEC(2003) 441.

[199] The inter-institutional seminar involved presentations from invited speakers, including the Chair and Vice-Chair of the EGE; *see http://ec.europa.eu/research/conferences/2003/bioethics/index_en.html* [Accessed October 1, 2008].

[200] Based on Art.166(4) EC.

> "the human embryos used for the procurement of stem cells must have been created before 27 June 2002[201] as a result of medically-assisted *in vitro* fertilisation designed to induce pregnancy, and were no longer to be used for that purpose".[202]

Furthermore,

> "the opinions of the European Group on Ethics in Science and New Technologies, and in particular those relating to research involving the use of human embryonic stem cells will be taken into account".[203]

During its plenary session of November 19, 2003,[204] the European Parliament deleted the cut-off date for the creation of the human embryos while inserting the criterion that the human embryos used for the procurement of stem cells,

> "must be 'supernumerary' early-stage (i.e. up to 14 days) human embryos (embryos genuinely created for the treatment of infertility so as to increase the success rate of *in vitro* fertilisation but no longer needed for that purpose and destined for destruction); such research may be funded provided that it is legally permitted in the Member State(s) where it will be conducted under the rules and strict supervision of the competent authority/ies" (Amendment 10).[205]

The Commission rejected Parliament's Amendment 10, because it had deleted the cut off date, which they stated they had included "to take account of ethical sensitivities".[206] The Council was due to make a final decision on December 3, 2003 but could not reach an agreement.[207] As a result, no Regulation on this matter was adopted and, after the moratorium from the original decision had lapsed, it was left to the Commission to decide upon the funding of stem cell proposals on a case-by-case basis.[208] Nevertheless, the distinction between different types and ages of embryos, that informed the proposals, follows the approach of the EGE. The political compromises that shaped FP6 thus point to a narrative on the ethical acceptability of embryos based on their source or type, and their age, that mirrors the ethical continuum established by the EGE in Opinion No.15.

[201] June 27, 2002 is the date of adoption by Parliament and Council of the Sixth Framework Programme.

[202] Proposal for a Decision amending decision 2002/834 on the specific programme for research, technological development and demonstration: "Integrating and strengthening the European research area" (2002–2006)COM (2003) 390 final, p.10.

[203] Amended Proposal for a Decision amending Decision 2002/834 on the specific Programme for research, technological development and demonstration: "Integrating and Strengthening the European Research Area" (2002–2006)COM (2003) 749 final, p.8.

[204] Proceedings of the sitting of the European Parliament November 19, 2003 OJ [2004] C87E/70.

[205] Integrating and strengthening the European research area, European Parliament legislative resolution on the proposal for a Council decision amending Decision 2002/834 on the specific programme for research, technological development and demonstration: "Integrating and strengthening the European research area" (2002–2006) [2004] OJ C87E/390.

[206] Amended Proposal for a Council Decision amending Decision 2002/834 on the specific Programme for research, technological development and demonstration: "Integrating and strengthening the European Research area" (presented by the Commission pursuant to Art.250(2) EC) (2002–2006)COM (2003) 749.

[207] 2550th meeting of the Council of the European Union Competitiveness (Internal Market, Industry and Research) CNS/2003/151. Also referenced as "15499/03".

[208] The Commission then asked the EGE for Opinion No.22, which assists its case by case decision making, see below.

The legal basis for ethical reviews in FP7[209] is the same as that in FP6.[210] Article 6 of Decision 1982/2006 states that, "[a]ll the research activities carried out under the Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles" and Art.10 (Art.15 in FP6) of the Rules of Participation, states that:

> "A proposal ... which contravenes fundamental ethical principles ... shall not be selected. Such a proposal may be excluded from the evaluation and selection procedures at any time."

Likewise, the three research areas excluded from funding under FP6[211] continue to be excluded under FP7.

The ethical review process of FP7 marks a major departure from that under FP6. All information required for an ethical review must be included in the proposal itself; the overriding objective being that ethics must be integrated into the research from the proposal preparation stage. Under FP7, all proposals for funding involving human embryonic stem cells will be automatically submitted to an ethical review panel to determine both the appropriateness of the source of human tissues and cells compared to viable alternatives, and the social and scientific benefits and drawbacks of using such tissues and cells, as recommended by the EGE in Opinion No.22. The recommendations on the ethical matters that must be included at the application stage (such as confirmation of the source of the human embryonic stem cells), and the "scientific" review (for instance, confirming that the research objectives could not be met without using human embryonic stem cells) point to a blurring of the boundary between "ethical" and "scientific/technical". This is another example of one of the central strategies used by the EGE to extend its role and influence.

Examining the Opinions and the legislation, we can discern EGE influence in refining and resolving the ethical problems in FP5, 6 and 7; in setting limits and conditions for human embryonic stem cell research, and processes of ethical review. However, the EGE's function has evolved and, via its role in FP7, has become more definitive. The EGE now plays an official part in the administration of this EU programme, and thus in the disbursement of EU funding. The EGE's role altered when President Barroso invited the Group to provide the Commission with an Opinion on the implementing measures required during the ethics review of research projects on human embryonic stem cells in FP7. The EGE now not only influences the legislation behind the programme, but has a direct hand in the execution of the programme itself. Thus the EGE has emerged as an important player in resolving, defining and legitimating the boundaries of ethical acceptability regarding human embryonic stem cell research within the EU Framework Programmes.

In addition to its influence in the European Union's legislative processes, the growing influence of the EGE can also be seen through EU administrative processes, in particular,

[209] Decision 1982/2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007–2013) [2006] OJ L412/1.

[210] See Decision 1513/2002.

[211] Research activity "aiming at human cloning for reproductive purposes" or "intended to modify the genetic heritage of human beings which could make such changes heritable" or "intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer".

its role within the European Union's Framework Programmes for research.[212] Up until recently, the influence of the EGE was limited to the legislative stages of the programmes. But Opinion No.22 of the EGE goes a step further. Not only were the EGE's Opinions "taken into account" when formulating legislation and policy for FPs 5, 6 and 7, but the EGE was also requested[213] for an Opinion on implementation of areas of this policy. It created guidelines used in ethics reviews of research projects under FP7 which deal with human embryonic stem cells. Thus in this example, the EGE is exercising a direct influence in the administration of FP7, the European Union's major support for research and development into its emerging technologies.[214] Again we see the EGE acting as a broker between the potential benefits to the EU economy from the development of biotechnological research, and the ethical distaste for some aspects of such research found in the regulatory structures of some Member States as well as in European civil society.

Conclusions: the EGE's role and influences

These three examples show that the EGE is playing an influential role in EU law-making and policy implementation. In the first example, on the regulation of intellectual property in biotechnology, the EGE's role is no less than to validate EU-level legislation. The EGE has significant influence over the substantive content of the legislative text, as eventually adopted. The second example, concerning medical uses of human tissues and cells, sees some influence on EU legislation, but perhaps more importantly, influence on the development of a policy community, which then uses the EGE's Opinions as an interpretative reference point in practical contexts at national level. In the third example, through developing substantive criteria for review of proposals for EU research funding, the EGE mediates between the European Parliament, representing civil society constituencies that are concerned about development of human embryonic stem cell research, and the European Commission, concerned to developed the "European Research Area".

In all three examples, the EGE mediates between the economic growth that the European Union seeks to achieve through new technologies, and the acceptance by Europe's populations of these new technologies as not only safe from the point of view of consumer

[212] The influence of the EGE in the area of the framework programmes can first be seen in FP5. See Annex of Decision 182/1999, "taking account of the competent authorities, in particular the European Group on Ethics in Science and New Technologies". The EGE is viewed as a "competent authority" in this area and the institutions acknowledge that their views are taken into account. This competence continues in FP6 with the announcement that: "Account will also be taken to the opinions of the European Group of Advisors on the Ethical Implications of Biotechnology (1991–1997) and the opinions of the European Group on Ethics in Science and New Technologies (as from 1998)." See Annex of Council Decision 2002/835. For FP7, see Decision 1982/2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007–2013) [2006] OJ L412/1 recital 30: "The opinions of the European Group on Ethics in Science and New Technologies are and will be taken into account."

[213] See letter sent from EC President Barroso to the EGE on November 22, 2006: "I would like to invite the European Group on Ethics to provide the Commission with an Opinion on the implementing measures required during the ethics review of research projects on human embryonic stem cells that will assure that the ethical rules and requirements are fully met."

[214] For further discussion, see A. Plomer, "The European Group on Ethics: A Trojan Horse in the European Union" (forthcoming) E.L.J.

protection, but also valid from the point of view of ethical values. The EGE is more than the provider of technical ethical information to the European Union's legislative and executive institutions. Increasingly, it is playing the role of broker between those parts of the EU legislature and executive, and stakeholders, such as industry, that seek to enhance the regulatory environment for the development of new biotechnologies within the European Union, and those parts of the legislature and European citizenry who are suspicious of the ethical adequacy of such a regulatory environment. The EGE's role increasingly is to warrant proposed EU legislation (and indeed administrative acts such as the disbursement of funding under FP7) as "ethically sound", according to a self-proclaimed shared set of common "European values".[215] It is therefore appropriate to discern whether its position within the European Union's legal order justifies such an influence.

Conclusion: The EGE in EU constitutional law

So, in the form of the EGE, a group of unelected professors of philosophy, theology, medical and health care ethics, genetics and public health, clinical pharmacology, plant molecular genetics, food safety, information management, and law,[216] with significant discretion over its approach, ethos and the substantive direction of its work, is exercising a brokering influence in EU legislation and administration of EU policy concerning biotechnologies. How does this group fit within the European Union's constitutionalised legal order?

In classical EU law, the legitimacy of EU legislative and administrative activity, and the accountability of the relevant actors, is based upon the constrained competence of the EU institutions,[217] the institutional balance between them,[218] and the detailed framework of EU administrative law.[219] These features of EU "constitutional law" are necessary to justify the normative power of binding EU secondary law (Regulations, Directives and so on), which enjoys primacy over conflicting national law.[220] EU law also governs the principles, procedures and practices of the EU Commission as administrative body.

Two documents have been particularly influential in framing discussions on legitimacy within EU legislative and administrative activity: the European Commission's 2001 White

[215] This is reflected in interviews with Günter Virt, June 19, 2007; Göran Hermerén, June 20, 2007; Inez de Beaufort, November 29, 2007; all members or former members of the EGE.

[216] Decision 2005/754.

[217] Articles 5 and 7 EC. See, for instance, S. Weatherill, "Competence Creep and competence control" (2004) 23 Y.E.L. 1.

[218] J.-P. Jacqué, "The Principle of Institutional Balance" (2004) 41 C.M.L. Rev. 383; L. Cram, "Introduction to Special Issue on the Institutional Balance and the Future of EU Governance: The future of the Union and the Trap of the 'Nirvana Fallacy' (2002) 15(3) *Governance: An International Journal of Policy, Administration and Institutions* 309 and the other contributions to that special issue; S. Prechal, "Institutional Balance: A Fragile Principle with Uncertain Contents" in T Heukels et al. (eds), *The European Union After Amsterdam: A Legal Analysis* (The Hague: Kluwer Law International, 1998); K. Lenaerts, "Some Reflections on the Separation of Powers in the European Community" (1991) 28 C.M.L. Rev. 11.

[219] See P. Craig, *EU Administrative Law* (Oxford: OUP, 2006), especially Ch.2; J. Schwartze, *European Administrative Governance*, revised 1st edn (London: Sweet and Maxwell, 2006).

[220] *Costa v Ente Nazionale per l'Energia Elettrica (ENEL)* (C-6/64) [1964] E.C.R. 585; [1964] C.M.L.R. 425; *Amministrazione delle Finanze dello Stato v Simmenthal SpA* (C-106/77) [1978] E.C.R. 629; [1978] 3 C.M.L.R. 263.

Paper on Governance[221] and the 2003 report to the President of the European Commission of the independent high-level study group chaired by André Sapir.[222] The White Paper proposed to reform the institutions involved in EU law and policy-making processes to foster greater openness, participation, accountability, effectiveness and coherence.[223] The Sapir report was concerned with providing guidance on making economic governance more efficient and effective by proposing "a strategy for delivering faster growth together with stability and cohesion in the enlarged Union".[224] The democratic standards raised in these documents—transparency, accountability, representativeness, effectiveness and efficiency—underpin the more detailed legislation that governs comitology procedures and agencies within the European Union's constitutional framework.[225] Although the extent to which the European Union's regulatory activities are legitimate and accountable has been questioned in the literature,[226] this legislation sets a binding legal framework

[221] European Commission, European Governance: A White Paper COM(2001) 428 final.

[222] A. Sapir, *An Agenda for a Growing Europe: Making the EU Economic System Deliver: Report of an Independent High-Level Study Group Established on the Initiative of the President of the European Commission* (Brussels: European Commission, 2003).

[223] European Governance: A White Paper, the "principles of good governance": p.10. See also the Commission's Towards a reinforced culture of consultation and dialogue: General principles and minimum standards for consultation of interested parties by the Commission COM(2002) 704 final, which sets participation, openness, accountability, effectiveness and coherence as its general principles (pp.15–18). See D. Obradovic and J.M. Alonso Vizcaino, "Good Governance Requirements concerning the Participation of Interest Groups in EU Consultations" (2006) 43 C.M.L. Rev. 1049; D. Curtin and R. Wessel (eds), *Good Governance and the European Union: Reflections on Conceptions, Institutions and Substance* (Antwerp: Intersentia 2005); G. Majone, "Ideas, Interests and Institutional Change: The European Commission debates the Delegation Problem" (2001) 4 *Cahier Europeens de Sciences Po*; Jean Monnet Working Paper No 6/01 Symposium, *Mountain or Molehill? A Critical Appraisal of the Commission White Paper on Governance*; K. A. Armstrong, "Rediscovering Civil Society: The European Union and the White Paper on Governance" (2002) 8(1) E.L.J. 102; C. Joerges and R. Dehousse (eds), *Good Governance in Europe's Integrated Market* (Oxford: OUP, 2002).

[224] Sapir, *An Agenda for a Growing Europe*, p.i.

[225] See Decision 1999/468; Decision 2006/512; Communication on the operating framework for the European regulatory agencies COM(2002) 718 final; Regulation 58/2003; Regulation 168/2007. See also, for instance, Regulation 768/2005 establishing a Community Fisheries Control Agency [2005] OJ L128/1; Regulation 2100/94 on Community plant variety rights [1994] OJ L227/1; Regulation 2062/94 establishing a European Agency for Safety and Health at Work [1994] OJ L216/1; as amended; Regulation 2007/2004 establishing a European Agency for the Management of Operational Co-operation at the External Borders of the Member States of the European Union [2004] OJ L349/1; Regulation 216/2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency [2008] OJ L79/1; Regulation 851/2004 establishing a European Centre for disease prevention and control [2004] OJ L142/1; Regulation 337/75 establishing a European Centre for the Development of Vocational Training [1975] OJ L39/1; Regulation 1641/2003 amending Regulation 1210/90 on the establishment of the European Environment Agency and the European Environment Information and Observation Network [2003] OJ L245/1, as amended; Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1; Regulation 1406/2002 establishing a European Maritime Safety Agency [2002] OJ L201/1; Regulation 460/2004 establishing the European Network and Information Security Agency [2004] OJ L77/1; Corrigendum to Regulation 881/2004 establishing a European railway agency [2004] OJ L220/3; Regulation 1049/2001 regarding public access to European Parliament, Council ad Commission Documents [2001] OJ L145/43; Interinstitutional Agreement between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management [2006] OJ C139/1.

[226] See Harlow, *Accountability in the European Union*; Scott, "Accountability in the Regulatory State" (2000) 27 *Journal of Legal Studies* 38; Andenas and Turk (eds), *Delegated Legislation and the Role of Committees in the EC*; Joerges and Vos (eds), *EU Committees*; Shapiro, "Problems of Independent Agencies in the United States and European Union" (1997) 4 J.E.P.P. 276; Lindseth, "Democratic Legitimacy and the Administrative Character of Supranationalism" (1999) 99 *Columbia Law Review* 628; Lindseth, "Weak constitutionalism" (2001) 21 *Oxford Journal of Legal Studies* 145; Majone, *Dilemmas of European*

for the objectives and scope of activities of the bodies concerned; their tasks; their membership, internal structures and working procedures; their relationship with stakeholders and the European public; and transparency of their work. To what extent are these matters determined by EU law for the EGE?

Objectives and scope of activities and tasks of the EGE

Occasionally the EU institutions, in particular the Commission, create ad hoc expert groups, to help with specialist areas of legislation. Sometimes the Commission will set up committees of an advisory nature to work for longer periods than this, in areas where it needs more continuous advice.[227] This pattern could also apply to the GAEIB/EGE at its inception. Biotechnology was new, and its regulation had not previously been examined by the European Union[228]; hence the Commission required expert advice in developing legislative proposals for this field.

There is no specific Treaty provision concerning ethics. A consultative ethics group in biotechnology could potentially fall under the remit of three specific substantive policy areas of the EC Treaty: Title XVIII on Research and Technological Development; Art.152 EC on Public Health; Art.153 EC on Consumer Protection. Potentially it could fall under Art.95 EC or the "general" legal basis provision in Art.308 EC. None of these was explicitly referred to in setting up the GAEIB, or the EGE in its first mandate. A Commission Decision[229] of May 2005, marking the first formal legal document establishing a mandate for the EGE, refers only to "the EC Treaty" as its legal basis.

The very general legal basis provision suggests an unsatisfactory position for the EGE. Recent case law suggests Art.95 EC as an appropriate legal basis. The EGE helps to prevent the emergence of obstacles to trade resulting from heterogeneous development of national laws,[230] as a:

> "Community body responsible for contributing to the implementation of a process of harmonisation in situations where, in order to facilitate the uniform implementation and application of acts based on that provision, the adoption of non-binding supporting and framework measures seems appropriate."[231]

If the EU legislature were to determine a more precise legal basis for the EGE, this would require a more detailed consideration of its status, the scope of its remit, and

Integration; Dehousse and Joerges, *Good Governance in an Integrated Market*; Joerges, "Integration through de-legalisation" (2008) 33 E.L. Rev. 291; Scharpf, *Governing in Europe. Effective and Democratic?*; Dehousse, "Regulation by Networks in the European Community" (1997) 4 J.E.P.P. 246; Arnull and Wincott, *Accountability and Legitimacy in the European Union*; Geradin and Petit, "The Development of Agencies at EU and National Levels" (2004) 23 Y.E.L. 137.

[227] For example in 1988 where the Commission was developing a proposal concerning common rules for the internal market in electricity, it set up two committees. One was made up of experts from the Member States and another of industry experts. They met regularly over a period of two and a half years and advised the Commission in this area. See G. Schäfer, "Linking Member State and European Administrations", in M. Andenas and A. Türk (eds), *Delegated Legislation and the Role of Committees in the EC* (Kluwer Law International, 2000), pp.9–11.

[228] See above.

[229] Decision 2005/383.

[230] *Parliament v Council* (C-436/03) [2006] E.C.R. I-03733; [2006] 3 C.M.L.R. 3 at [39].

[231] *United Kingdom v Parliament* (C-217/04) [2006] E.C.R. I-03771; [2006] 3 C.M.L.R. 2 at [44].

the tasks it may legitimately carry out. For instance, as we saw above, the GAEIB/EGE regularly blurs the concept of "ethical" to include matters that are "technical/scientific".[232] The imprecision of the legal basis of the EGE reduces the legal constraints that are set on its activity. By contrast, for instance, the Regulation establishing the Fundamental Rights Agency sets in legislative form its objective, scope of activity, tasks, and areas of activity.[233] At present, the EGE enjoys considerable autonomy in this respect, with only a brief provision in the Commission Decision establishing its mandate covering its "mission".[234]

The EGE's membership

Until the EGE's most recent mandate, the documentary record states that its members were appointed by the Commission. However, in the 2005–2009 mandate, this power was transferred solely to the Commission President. When the Commission was questioned about this change in procedure, they responded that, informally, this had always been the case and this document merely formalised the procedure.[235] New members of the EGE are recruited through an open call of interest on the website of the EGE for applications. Additional applications from other channels will also be taken into consideration in the selection procedure.[236] What these "other channels" are is not entirely clear. Members must have a university degree in ethics, philosophy, theology, law or science and relevant, internationally recognised high-level experience.[237] They are expected to attend at least four meetings of the EGE a year.[238]

There is no legal obligation on members to make statements of their interests, or even to declare any conflict of interest in a particular Opinion.[239] Again, this contrasts with the position of EU agencies. For instance, specific legislative provisions require independence of the members of the Fundamental Rights Agency, including an obligation on the members of the Management Board, Scientific Committee and the Director to make a statement of interests.[240] Given the influence and potential future influence of the EGE's Opinions on law and policy, this level of transparency would seem to be desirable, so

[232] For instance in its influence on the Biotechnology Directive, the blurring between "ethics" and technical legal matters of patent law; in its "continuum" approach to (the science of) stem cells, which is now embedded in both the relevant legislation and policy implementation; its blurring of ethical and scientific review processes under FP7.

[233] Regulation 168/2007 Arts 2, 3, 4 and 5 respectively.

[234] Decision 2005/383 Art.2.

[235] P6_RE(2006)0430. Answers given by Mr Barroso on behalf of the Commission on March 17, 2006 to Written Parliamentary Questions by Marco Pannella on Criteria and Methods for the selection of the members of the European Group on Ethics in Science and New Technologies (EGE), answer no.1, searched for and accessed online at the European Parliament Register of Documents: *http://www.europarl.europa.eu/RegWeb/application/registre/searchResult.faces* [Accessed October 1, 2008].

[236] Decision 2005/383 Art.3(2).

[237] P6_RE(2006)0430 answers given by Mr Barroso on behalf of the Commission to Parliamentary questions by Marco Pannella on criteria and methods for the selection of the members of the European Group on Ethics in Science and New Technologies (EGE), answer no.3, searched for and accessed online at the European Parliament Register of Documents: *http://www.europarl.europa.eu/RegWeb/application/registre/searchResult.faces* [Accessed October 1, 2008].

[238] Decision 2005/383 Art.4(4).

[239] Although our interviewees stated that members are required to declare any conflict of interest; Interview Maurizio Salvi, June 20, 2007.

[240] Regulation 168/2007 Art.16.

that the other EU institutions, and wider civil society, can determine the basis on which the members are reaching their Opinions.

Officially, the members of the EGE represent themselves only.[241] They are to remain independent and to simply represent their own particular views and conscience above all else. Formally speaking, the EGE members are appointed *ad personam*.[242] However, the President is concerned to balance the EGE in terms of geographical origin, gender and areas of expertise.[243] This practice suggests a representative element in the rationale behind the selection of the EGE's membership. There might be good reasons to ensure that different geographical constituencies are represented in the EGE, particularly if these map to broader cultural or historical outlooks that differ from one another with respect to ethics. But at present, the need to ensure such representation (or alternatively, an explanation of why this is not necessary) is not codified in any respect in the European Union's legal framework.

The EGE's internal structures, working procedures, and consultation practices with institutional actors, stakeholders and the European public

By and large, the EGE creates its own rules of procedure.[244] It is legally obliged only to elect a Chair and Vice-Chair from among its members,[245] and to agree its work with the President of the Commission,[246] although it can also initiate its own Opinions.[247] Different Chairs have adopted different approaches, for instance on how discursive the meetings are; the selection of the rapporteurs for each Opinion; encouraging dissenting Opinions rather than proceeding by unanimity; the style, structure and length of the Opinions themselves; and the use of experts and round table discussions.[248]

The EGE is under a formal obligation to "establish close links" with the Commission departments involved in the topic under consideration.[249] Otherwise, it is under no formal obligation to consult either other institutional actors within the European Union or its Member States, stakeholders, or the wider European public. Under the latest mandate, the EGE has developed links with the Commission's Interservice Platform (via its Secretariat) which provides co-ordination across all 19 Commission services.[250] Although not required, the EGE has adopted the practice of consulting experts, from outside its membership, in all the specific technical areas involved in a particular Opinion. For instance, in developing its Opinion No.16 on patenting inventions involving stem

[241] Decision 2005/383 Art.3(2). This point was emphasised in many of our interviews: Günter Virt, June 19, 2007; Göran Hermerén, June 20, 2007; Pere Puidomènech Rosell, June 20, 2007; Peter Whittaker, August 8, 2007; Catherine Labrusse-Riou, October 18, 2007. One interviewee questioned the word "representing" itself: Inez De Beaufort, November 19, 2007.

[242] Decision 2005/383 Art.3(2).

[243] Interview with Maurizio Salvi, June 20, 2007; Michael Rogers, October 24, 2007.

[244] Decision 2005/383 Art.4(7).

[245] Decision 2005/383 Art.4(1).

[246] Decision 2005/383 Art.4(2).

[247] Decision 2005/383 Art.2.

[248] Interview with Maurizio Salvi, June 20, 2007; Günter Virt, June 19, 2007; Michael Rogers, October 24, 2007; Peter Whittaker, August 8, 2007.

[249] Decision 2005/383 Art.4(5).

[250] These include translation, research, international affairs, legal services: interview with Maurizio Salvi, June 20, 2007.

cells, the EGE held a hearing with Members of the European Parliament, experts and representatives of industry, research, patients and environment.[251] In practice, the EGE also takes note of opinions and recommendations of national ethics bodies in the Member States.[252]

Again, a comparison with the Fundamental Rights Agency suggests that the EGE is significantly less constrained in its working practices. For instance, the working methods of the Fundamental Rights Agency are specified in its founding legislation, including an explicit list of the national and European institutions whose information and activities the Agency must take into account.[253] Further, the Fundamental Rights Agency is formally obliged to consult with "civil society" through a legislatively specified "Fundamental Rights Platform". By contrast, the GAEIB/EGE have increased the inclusion of the public and strengthened ties with national ethics committees through ad hoc arrangements. These interactions have expanded with each subsequent mandate. The current mandate obliges the EGE only to establish closer links with Commission departments and to organise public round table debates,[254] although it does explicitly permit the EGE to establish closer links with national ethics committees in Member States and applicant countries; and also to consult experts, initiate studies and set up working groups.[255] In all these respects, therefore, in terms of the formal, legal position, the position of EU agencies thus offers a stark contrast to the (un-legitimated—at least in the senses of administrative law) self-generated working methods and practices of the EGE.

The independence of the EGE over its procedures provides a significant degree of discretion within the EGE, in particular on the part of the Chair, not only to determine its practical working, but also to influence its focus and future direction. Essentially, the EGE has a significant independent power over its own remit. The lack of formal expression of the EGE's position, until 2005, also allowed a degree of flexibility over external interpretations of its remit.[256]

Transparency of the EGE's work

Transparency of regulatory bodies is an essential requirement in securing accountability, legitimacy, efficiency and effectiveness. Again looking at the Fundamental Rights

[251] See activities of the EGE 2000–2005 available at *http://ec.europa.eu/european_group_ethics/archive/2001_2005/activities_en.htm* [Accessed October 1, 2008].

[252] For instance, the EGE participates in the Forum of National Ethics Councils, where all 27 Member States are represented; interview with Maurizio Salvi, June 20, 2007. The work of the UK Nuffield Foundation was mentioned as particularly useful or influential; interview with Maurizio Salvi, June 20, 2007; Pere Puidomènech Rosell, June 20, 2007.

[253] Including EU institutions and bodies, the Council of Europe and the Organisation for Security and Co-operation in Europe, Regulation 168/2007 Arts 6(2)(a)–(c) and 9; national human rights agencies in the Member States of the EU, Regulation 168/2007 Art.8(2); and civil society institutions, through a cooperation network (the Fundamental Rights Platform), whose composition is specified in the Regulation Art.10.

[254] Decision 2005/383 Art.4(5).

[255] Decision 2005/383 Art.4(4).

[256] For instance, the EGE was asked (although declined) to give an Opinion on the EU Charter of Fundamental Rights. Instead, it gave a "Report": EGE, "Citizen's Rights and New Technologies: A European Challenge. *Report of the European Group on Ethics in Science and New Technologies on the Charter of Fundamental Rights related to technical innovation"* as requested by President Prodi on February 3, 2000 EGE website: *http://ec.europa.eu/european_group_ethics/docs/prodi_en.pdf* [Accessed October 1, 2008].

Agency, we find legislatively enshrined specific obligations on transparency and access to documents, data protection, and scrutiny by the European Ombudsman.[257] The EGE is obliged to publish its Opinions[258] and all are available on its website.[259] The Chair must publish a report at the end of each mandate.[260] However, the EGE's working sessions are private.[261] The rationale for this is so that the members can have a free and frank exchange of views in their deliberations, and also so that they can change their minds over time.[262] Nevertheless, the EGE has developed general principles of transparency, keeping proceedings as open as it deems possible, for instance, with round table discussions, and recently the publication of these, and other materials received by the EGE, on the EGE website.[263] Still, the lack of formal oversight by the usual structures of administrative law suggests that the position of the EGE in this respect could be improved.

The EC Treaty provides for access to Commission documents (and those of Council and European Parliament),[264] and this is enshrined in the EU Charter of Fundamental Rights 2000.[265] Although the Treaty provisions have been held to apply to a Council working group,[266] such working groups are made up of civil servants, whereas the EGE's members are independent of the Commission and of the governments of the Member States. Regulation 1049/2001 on public access to Parliament, Council and Commission documents applies to "all documents held by an institution, that is to say documents drawn up or received by it and in its possession".[267] This could be interpreted to include all the work of the EGE, which might be said to be "in the possession of" the Commission's Bureau of European Policy Advisors, which is responsible for organising the work of the EGE and its secretariat.[268] However, apparently, the internal documents of the EGE cannot be accessed from within the Commission.[269] Moreover, a Commission proposal from April 2008[270] to amend Regulation 1049/2001 notes that many respondents to its consultation process leading to the proposal suggest that the scope of the Regulation should be extended to "all EU institutions, bodies and agencies". The Commission states

[257] Regulation 168/2007 Arts 16, 17, 18 and 19 respectively.
[258] Decision 2005/383 Art.4(6).
[259] *http://ec.europa.eu/european_group_ethics/index_en.htm* [Accessed October 1, 2008].
[260] Decision 2005/383 Art.4(8).
[261] Decision 2005/383 Art.4(3).
[262] Interview with Michael Rogers, October 24, 2007.
[263] Interview with Maurizio Salvi, June 20, 2007.
[264] Article 255(1) EC.
[265] Article 42 EUCFR [2007] OJ C303/1.
[266] *Hautala v Council* (T-14/98) [1999] E.C.R. II-2489; [1999] 3 C.M.L.R. 528; *Council v Hautala* (C-353/99 P) [2001] E.C.R. I-9565; [2002] 1 C.M.L.R. 15.
[267] Regulation 1049/2001 on public access to Parliament, Council and Commission documents [2001] OJ L145/43.
[268] Regulation 1049/2001 provides an exception for "third party documents", requiring the Commission to consult the third party as to whether an exception on various grounds, including individual privacy or integrity, and commercial interests, might apply. Documents considered by the EGE in the process of its deliberations might fall within one of these categories. The Commission would therefore be obliged to consult the EGE, as a third party, before determining whether the exception applied: *IFAW Internationaler Tierschutz-Fonds GmbH v Commission* (T-168/02) [2004] E.C.R. II-4135; [2005] 2 C.M.L.R. 28 at [55]–[56]; *Scippacercola v Commission* (T-187/03) [2005] E.C.R.-II-1029; [2005] 2 C.M.L.R. 54 at [54]–[55]; *Sweden v Commission* (C-64/05 P), unreported, December 18, 2007 at [79].
[269] Interview with Michael Rogers, October 24, 2007.
[270] Commission Proposal for a Regulation regarding public access to European Parliament COM(2008) 229 final.

that this is not feasible under the current Treaties. However, it proposes a definition of "third party" as,

> "any natural or legal person, or any entity outside the institution concerned, including the Member States, other Community or non-Community institutions and bodies and third countries".[271]

This proposed definition suggests that "other Community bodies", which is probably the best definition of the EGE's position, do not fall within the current Regulation.[272]

Thus, it is not entirely clear whether either of these general provisions of EU law concerning transparency could be enforced against the EGE. Following a review by the European Ombudsman,[273] specific legislation clarifying the position concerning transparency and access to the documents of a range of EU bodies, including agencies, has been adopted.[274] There is no equivalent legislation applicable to the EGE, so, with the exception of its formal Opinions and its Chair's report, its own assessment of which of its working documents can be made transparent remains without clear legislative oversight.

Conclusion: The EGE as a "grey governance" body

Situated at the intersection of law, bioethics and economic policy, the EGE plays an ambiguous role in the European Union's legal order. In classical constitutional law terms, the European Union's law-making legitimacy is both derived from and constrained by its constituent Treaties and secondary legislation. The regulation of biotechnology by the European Union occupies an interesting position within the on-going "democratic deficit" debate. On the one hand, the version of European competitiveness apparently mandated by the Treaties suggests that law and policy-making to enhance the expansion of biotechnologies as envisaged by the European Commission is an entirely legitimate activity for the European Union. At the same time, however, there is a problematic lack of citizen support for such expansion. The EGE plays a role in bolstering the acceptance of emerging biotechnologies, by supplying authoritative normative endorsement to legislation that supports the activities of market actors within the biotechnology industry. But at the same time, its constitutional status is at best "grey", given that it has no firm basis in the European Union's constituent Treaties, or the legislative structures developed to enhance the legitimacy, transparency, accountability, representativeness, effectiveness and efficiency of the European Union's legislative and executive decision-making.

[271] Commission Proposal for a Regulation regarding public access to European Parliament proposed new Art.3(b).

[272] Our interviews also suggested that the EGE is quite independent of the Commission; interview with Maurizio Salvi, June 20, 2007.

[273] *Special Report from the European Ombudsman to the European Parliament following the own-initiative inquiry into public access to documents* (616/PUBAC/F/IJH) [1998] OJ C44/9.

[274] P. Craig and G. de Búrca, *EU Law: Texts Cases and Materials* (Oxford: OUP, 2007), p.563.