AN OVERVIEW REPORT ON

BIOETHICS IN THE EUROPEAN UNION

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FOREWORD

This publication aims to serve as an overview of the policy of the European Union concerning bioethical issues.

Generally speaking, bioethical matters are not within the purview of the EU. Even today the EU does not possess the legislative competence to act in areas of policy where bioethical questions are of central importance. Yet, the development of new technologies on the one hand, and the process of greater integration on the other, are creating a practical necessity for the EU to assume a certain role of responsibility and to take decisions within this domain.

The report aims to be a type of compendium on EU bioethical matters and a summary of the skills and knowledge possessed by Katharina Schauer, the COMECE official who, over the last 8 years, has been charged with the role of monitoring EU decisions in the field of bioethics and research. The report aims to describe the legal bases upon which EU decisions are taken and to provide an explanation of the instruments allowing the EU to be active in the bioethics field even beyond its competencies. In the second part of the document you will find a list of different bodies established within the institutions of the EU, either on a permanent or ad hoc basis, in order to deal with ethical problems. The third part of the report provides an overview of major bioethical themes within EU legislation either currently in force or presently under discussion (as at July 2009).

In my opinion this report reveals the importance of bioethical issues within EU policy and the essential role of the work of COMECE in this crucial field during last decade.

Fr. Piotr Mazurkiewicz
General Secretary of COMECE

INTRODUCTION

The Secretariat of COMECE has been monitoring EU[1] policies which touch on bioethical questions for over a decade. In fact, it was in the context of the EU Directive on Patenting of Biotechnological Inventions (adopted in 1998) as well as in the 5th Research Framework Programme (also adopted in 1998) that such questions became apparent during the debates in the EU institutions. Since then, the debate on bioethical issues at the EU level has developed rapidly.

In 1996, the Bioethics Reflection Group of the COMECE Secretariat was founded. The opinions issued by this multidisciplinary group of Professors were published in 2008 under the title "*Science and Ethics*", and can be obtained from the COMECE Secretariat.

This Report proposes a review of the state of play of the debate on bioethics in the framework of the EU:

Following an introduction on the notion of human dignity into the European legal context (part 1), an overview will be undertaken of those EU competences where bioethical issues are most likely to arise (part 2).

Subsequently, the main "players" in the European institutions that are involved in bioethical debates will be presented (part 3).

The next section (part 4) outlines a selection of EU legislation and other measures which have a more or less direct impact on bioethical issues.

The final part (part 5) proposes a conclusion taking into account COMECE's future priorities in the fields of research policy and bioethics at EU level.

[1] As this Report is not a purely legal text, the term " EU" is used throughout the text as a non-technical term to refer to the EU or the EC.

HUMAN DIGNITY

Human dignity is one of the central values of the EU and its Member States. Yet, whilst all Member States agree on the abstract concept of human dignity, the divergence of positions taken by different EU Member States when it comes to bioethical issues is striking. This has been obvious for several decades in the way the question of abortion was dealt with in different Member States; also regarding euthanasia, some European states have taken a more liberal stance than others.

The question of human dignity at the very beginning of human life has become more urgent in the light of new research which renders the use of human embryos both possible for and of interest to basic research as well as for testing methods or possible future therapeutic applications. Some European states tend to protect human life from the moment of conception whilst others introduce a distinction between a human being and a human person, thereby allowing for certain uses of human beings in their first stages of development, or else they take the view that the human embryo has a "growing value" alongside his/her development as a human being.

NO COMMON "LAW" ON BIOETHICS IN EUROPE

At the European level, there is no common legal framework for the protection of human dignity and that of the human embryo in particular.

Council of Europe

The Council of Europe was the first international organisation to adopt a binding international agreement dealing with the ethical challenges of new biomedical technologies: On 4 April 1997, the '*Convention on Human Rights and Biomedicine*' (known as the "Oviedo Convention") [2] was opened for signature and entered into

[2] ***Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine***, Oviedo, 4 April 1997; CETS No.: 164, full text: http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm.

force on 1 December 1999. The Convention has now been ratified by 22 of the 45 member states of the Council of Europe[3], and signed by an additional 12 member states[4] who have not yet ratified. However, many of the bigger member states of the Council of Europe have not ratified; for example France, Germany, Great Britain, Italy, and Sweden.

The Convention aims at providing a common, minimum level of protection in the field of biomedical research throughout Europe.

The Convention gives precedence to the human being over the sole interest of science or society:

> *Article 2 – Primacy of the human being*
>
> *The interests and welfare of the human being shall prevail over the sole interest of society or science.*

However, no agreement was achieved when it came to the treatment of human embryos in research. As a "minimum standard", the Oviedo Convention requires that no human embryos be *produced* for research purposes; whether or not to allow for the use of so-called surplus human embryos is left up to the Member States who have signed the Convention:

> *Article 18 (Research on embryos in vitro)*
>
> 1. *Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo.*
> 2. *The creation of human embryos for research purposes is prohibited.*

Moreover, the selection of a future child's sex is in principle not allowed; however, where the aim is to avoid a "serious hereditary sex-related disease", it is not prohibited:

The Convention entered into force on 1 December 1999. For the list of signatories see: www.conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=2&DF=6/22/2009&CL=ENG

[3] Bosnia/Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Georgia, Greece, Hungary, Iceland, Lithuania, Moldova, Norway, Portugal, Roumania, San Marino, Slovakia, Slovenia, Spain, Switzerland, Turkey.

[4] Finland (1997), France (1997), Italy (1997), Latvia (1997), Luxembourg (1997), Montenegro (2005), The Netherlands (1997), Poland (1999), Serbia (2005), Sweden (1997), The Former Republic of Macedonia (1997), Ukraine (2002).

> *Article 14 (Non-selection of sex)*
>
> *The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided.*

Yet, the value of the Oviedo Convention is limited by the fact that a number of Council of Europe member states did not adhere even to these standards, for example, Great Britain, Belgium, Sweden. Given their liberal positions when it comes to ethically contentious research, the Oviedo Convention could in their view hinder the development of research in this area. Other member states, such as Germany, have not signed the Convention because it is considered to be too liberal.

The Oviedo Convention is the basis for a number of "additional protocols" dealing with different aspects of biomedicine. To date, four additional protocols have been introduced: one prohibiting the cloning of human beings (in force since 1 March 2001)[5], one on the transplantation of organs and tissues of human origin (in force since 1 May 2006)[6], one on biomedical research (in force since 1 September 2007)[7] and one on genetic testing for health purposes[8] (not yet in force). Another additional protocol on the protection of the human embryo had been planned, but was never achieved due to

[5] ***Additional Protocol to the Convention on Human Rights and Biomedicine, on the Prohibition of Cloning Human Beings***, Paris, 12.I.1998, CETS No.: 168; full text: http://conventions.coe.int/Treaty/en/Treaties/Html/168.htm.
The Protocol entered into force on 1 March 2001. For the list of signatories see: www.conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=168&CM=1&DF=6/22/2009&CL=ENG

[6] ***Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin***, CETS No.: 186, Strasbourg, 24.I.2002; full text: http://conventions.coe.int/Treaty/en/Treaties/Html/186.htm.
The protocol entered into force on 1 May 2006. For the list of signatories see: www.conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=186&CM=1&DF=6/22/2009&CL=ENG

[7] ***Additional Protocol to the Convention on Human Rights and Biomedicine concerning biomedical research*****,** CETS No.: 195, Strasbourg, 25.I.2005; full text: www.coe.int/t/dg3/healthbioethic/Activities/01_Oviedo%20Convention/195%20Protocole%20recherche%20biomedicale%20e43.pdf.
The protocol entered into force on 1 September 2007. For the list of signatories see: www.conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=195&CM=2&DF=6/22/2009&CL=ENG

[8] ***Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes*****,** CETS No.: 203, Strasbourg 27.XI.2008, full text: http://conventions.coe.int/Treaty/EN/Treaties/Html/203.htm.
The protocol is not yet in force. For the list of signatories see: www.conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=203&CM=1&DF=6/22/2009&CL=ENG.

the very divergent positions of the member states of the Council of Europe on the status of the human embryo.

European Union

When it comes to the European Union, the ***Charter of Fundamental Rights***[9] is the EU's main framework document for fundamental rights and for some bioethical questions. The Charter establishes an integral catalogue of fundamental rights in the European Union. It encompasses not only civil and political rights, but also social and economic rights and principles as well as principles addressing the challenges of modern society (bioethics, data protection, proper administration). The Charter places the inviolability of "human dignity" in its first article, thus making it the foundation of the whole text:

> *Article 1: Human dignity*
>
> *Human dignity is inviolable. It must be respected and protected.*

The Charter recognises a "right to life" in its Article 2; however, the Member States do not agree as to whether or not "everyone" includes the human embryo:

> *Article 2: Right to life*
>
> 1. *Everyone has the right to life.*
> 2. *No one shall be condemned to the death penalty, or executed.*

When it comes to the issue of human cloning, it is noteworthy that, unlike the Oviedo Convention of the Council of Europe (see above), the Charter of Fundamental Rights does not prohibit the creation of human embryos for research purposes. It only prohibits reproductive cloning of human embryos:

> *Article 3: Right to the integrity of the person*
>
> 1. *Everyone has the right to respect for his or her physical and mental integrity.*
> 2. *In the fields of medicine and biology, the following must be respected in particular: … (d) the prohibition of the reproductive cloning of human beings.*

In the negotiations, not all Member States were able to agree on prohibiting any creation of human embryos for research purposes; on the other hand, several Member States insisted that a lack of a specific provision or prohibition does not imply a justification for the creation of human embryos for research, for example by way of so-called therapeutic cloning. The Explanations on the Charter[10] (prepared by the Bureau of the Convention) explicitly state that whilst Article 3 of the Charter prohibits only reproductive cloning: "*It neither authorises nor prohibits other forms of cloning. Thus it does not in any way prevent the legislature from prohibiting other forms of cloning"*.

This reveals a *de facto* split among EU Member States when it comes to the interpretation of the fundamental Articles 1 - 3 of the Charter of Fundamental Rights.

Legal value of the Charter of Fundamental Rights

The Charter was proclaimed by the European Council at Nice in December 2000; at that time, and until now, it has been merely a political declaration. The European Court of Justice in fact did not refer to the Charter of Fundamental Rights until June 2006[11]: although, before that date, it was often referred to by the Court of First Instance and the Advocates General. In acknowledging the fact that the Charter is not a legally binding instrument, the Court stated[12] clearly that the principal aim of the Charter is not to create any new rights but to reaffirm '*rights as they result, in particular, from the constitutional traditions and international obligations common to the Member States, the Treaty on European Union, the Community Treaties, the [ECHR], the Social Charters adopted by the Community and by the Council of Europe and the case-law of the*

[9] ***Charter of Fundamental Rights of the European Union***, OJ 2007/C 303/01, 14 December 2007; full text: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2007:303:0001:0016:EN:PDF

[10] Explanations on the Charter; full text: www.europarl.europa.eu/charter/convent49_en.htm

[11] See e.g. Case C-540/03, Parliament v Council, Case C-411/04 P, Mannesmannröhren-Werke AG v Commission, Case C-303/05, Advocaten voor de Wereld, Case C-432/05, UNIBET (London) LTD v Justitiekanslern,

[12] Case C-540/03, Parliament v Council [2006].

Court and of the European Court of Human Rights. Therefore, even as a "political declaration", the Charter has had a significant impact on EU law.

If the Treaty of Lisbon enters into force, the Charter of Fundamental Rights will become an integral part of the Treaty (Article 6), and will be legally binding on the EU institutions, bodies, offices and agencies "*with due regard for the principle of subsidiarity*", and for all EU policy areas. It will be binding on Member States as well when they are implementing EU law (Article 51 paragraph 1). Thus, the European Court of Justice will have jurisdiction to hear actions brought against a Member State for infringing the Charter when implementing Community law. Having said this, the Charter does not extend the field of application of EU law or establish any new power or task for the EU (Article 51 paragraph 2).

Specific measures (called opt-outs) for the United Kingdom and Poland were introduced in a Protocol No 30[13] added to the Treaty of Lisbon. The Preamble to the Protocol explicitly refers to Article 6 of the Treaty on European Union and it confirms that both the UK and Poland are bound by the *fundamental rights, as guaranteed by the ECHR and as they result from the constitutional traditions common to the member states, which constitute general principles of the Union's law*.

Article 1 (1) of the Protocol prohibits the European Court of Justice from making a judgement that Polish or British laws are inconsistent with the provisions of the Charter. However, it does not exclude the possibility of the Charter being used as an interpretative tool. This opt out is further weakened in Article 1 paragraph 2 declaring that, with regard to social and economic rights, the Charter will not create "justiciable rights" applicable to Poland or the UK. Therefore, all other rights are treated as justiciable.

As a result of these limitations, the "opt out" is to be considered as having more political than legal standing.

[13] Protocol (No 30) on the application of the Charter of Fundamental Rights of the European Union to Poland and to the United Kingdom, Official Journal of the European Union, 2008 C 115/313, 9 May 2008, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:115:0201:0328:EN:PDF.

EU COMPETENCES RELATING TO BIOETHICS

Ethical and bioethical questions in general were not seen, for a long time, as an issue for the European Community, given that it was primarily an economic community. Even today, the EU does not have any legislative competence for policy areas in which bioethical questions are central. Rather, the principle of subsidiarity applies; that means that it is the EU Member States that take the fundamental decisions in this area, such as whether or not to allow human embryo research in their country.

However, it has become more and more evident that:

- bioethical questions and the new developments in biomedical research are of a transnational nature;
- EU decisions in different policy fields impact upon the bioethical positions of the Member States (e.g. the Directive on the legal protection of biotechnological inventions which touched on the question of the possibility of granting patents on human embryos or DNA sequences).

The following gives an overview on the main fields of EU competences where bioethical issues tend to arise.

I. MAIN AREAS OF EU COMPETENCE WHERE BIOETHICAL ISSUES ARISE

1.1 Internal Market: Article 95 EC Treaty[14]

According to Article 95 (1), the Council of Ministers together with the European Parliament can adopt "*measures for the approximation of the* [national] *provisions*" if they "*have as their object the establishment and functioning of the internal market*."

[14] See the Annex for the text of Articles 94, 95 EC Treaty

Co-decision procedure according to Article 95 (1), 251 EC Treaty

The legislative procedure is the *co-decision procedure according to Article 251 EC Treaty* which implies that the European Parliament and the Council of Ministers must make a joint decision on a proposal put forward by the European Commission.

First reading: The European Parliament elaborates its opinion on the Commission proposal (first in the Committee, then in the plenary). After having received the European Parliament's opinion, the Council of Ministers must reach a common position by qualified majority. If the Council of Ministers does not accept all amendments proposed by the European Parliament, a second reading is necessary.

Second reading: The European Parliament can either adopt the common position of the Council of Ministers, or reject the common position (by an absolute majority of its component Members), or propose amendments to the common position of the Council of Ministers; these amendments require again an absolute majority of the European Parliament's component Members; also, certain restrictions apply to allow for the possibility of the European Parliament proposing new amendments. After the European Parliament's second reading, the Council of Ministers can either approve all the amendments of the European Parliament (usually by qualified majority; only if the European Commission delivered a negative opinion, unanimity is required in the Council of Ministers) or it has to convene a meeting of the Conciliation Committee.

Conciliation Committee: A proposal is elaborated in the Conciliation Committee; the joint text is approved by the European Parliament, acting by an absolute majority of the votes cast, and the Council, acting by a qualified majority.

Choice of legal instrument on the basis of Article 95

The European Commission can choose between different legal instruments, in particular whether it chooses to propose a Directive or a Regulation. According to Article 249 EC Treaty[15], a "Regulation" is "*binding in its entirety and directly applicable in all*

[15] See the Annex for the text of Article 249 EC Treaty

Member States"; a "Directive" is also "binding", "*but shall leave to the national authorities the choice of form and methods*". In general, and in accordance with the principle of subsidiarity, the European Commission should choose the less invasive legal instrument, unless the "stronger" legal instrument (the Regulation) is required to achieve the purpose of the legal basis. Article 95 can be considered as a "strong" legal basis, which allows for the use of the legal instrument of a Regulation.

Restrictions on national provisions

The choice of Article 95 as the legal basis implies a particular limitation on Member States to maintain or to introduce national provisions restricting the internal market: After the adoption of a harmonisation measure, a Member State may only maintain national provisions for a listed set of reasons set out in Article 95 paragraph 4, Article 30 EC-Treaty: such as on grounds of, for example, public morality, public policy or public security. As for the *introduction* of national provisions after the adoption of a harmonisation measure, this can only be justified, according to Article 95 paragraph 5, if it is based on "*new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure"*. Any national provision which does not fall under one of the categories would be illicit as it might undermine the aim of the legal basis which is to establish an "*area without internal frontiers in which the free movement of goods, persons, services and capital is ensured*" (Article 95 paragraph 1, Article 14 EC Treaty).

A number of legislative provisions with bioethical relevance are based on this Article, for example:

- *Directive 98/44/EC on the legal protection of biotechnological inventions (see 1.1.A, p.33).*
- *Regulation (EC) No. 1394/2007 on advanced therapy medicinal products (see 1.1.D, p.39)*
- *Proposal for a Directive on the protection of animals used for scientific procedures (see 2.1, p.60).*

1.2 Public Health: Article 152 EC Treaty[16]

There is another legal basis which can imply bioethical questions and which relates to health: namely, Article 152 EC Treaty. When compared with Article 95 EC Treaty, Article 152 provides the EU with a more limited competence, as it clarifies that Member States have the main responsibility for health policy and provision of healthcare to European citizens. Any Community action in the field of public health "*shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care*" (Article 152 (5)).

However, Article 152 requires that a "*high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities*". Furthermore, it states that "***Community action ... shall complement national policies***, (and) *shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health*" (Article 152 (1)). Article 152 (2) provides the European Commission with the mandate to "***take any useful initiative to promote ... coordination***" between the Member States.

More concretely, Article 152 (4a) provides the European Community with the direct competence to adopt "***measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives***". This provision also explicitly mentions the possibility for the Council of Ministers, acting by qualified majority, to adopt – on a proposal of the European Commission – ***recommendations*** for the purposes of Article 152. A recommendation is a non-binding instrument (Article 249 EC Treaty).

The applicable legislative procedure is again the *co-decision procedure* according to Article 251 EC Treaty (see above 1.1). The Council of Ministers decides by qualified majority.

[16] See the Annex for the text of Article 152 EC Treaty

A number of legislative and other measures are based on this Article, in particular:

- *Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing of human tissues and cells* (see 1.2, p.45).

- *Council Recommendation on action in the field of rare diseases* (adopted on 9 June 2009) (see 3.3, p.80)

Choice of Article 152 EC Treaty as the legal basis

Whether the choice is between Article 152 or Article 95 EC Treaty has implications for the legal constraints imposed on Member States: due to the limited competence provided to the EC by Article 152, a directly binding Regulation could hardly be based on Article 152. However, Article 95 EC Treaty is a suitable legal basis for a Regulation. Moreover, Article 152 EC Treaty does not imply the restrictions for diverging national provisions which are implied by Article 95 EC Treaty (see above 1.1).

1.3 Research and Technological Development: Articles 163-173 EC Treaty[17]

Another legal basis which has triggered bioethical debates in the past concerns the EU's research policy: articles 163ff EC-Treaty. The Treaty provides for the *objective* of European Communities' research policy to strengthen "*the scientific and technological bases of Community industry and encouraging it to become more competitive at international level, while promoting all the research activities deemed necessary by virtue of other chapters of this Treaty*".

The main Community instrument is the adoption of a multiannual framework programme according to Article 166ff EC-Treaty; this programme is proposed by the European Commission and adopted jointly by the Council of Ministers and the European Parliament by way of the co-decision procedure. (see 1.4.B, p. 48)

The important role for research in this context is reflected by its budget: The current ***7th Programme for Research and Technological Development (FP7)*** has a budget of approximately 50 billion € over a period of 7 years (2007-2013); this represents roughly 6 % of the overall budget of the EU according to the EU's Financial Perspective 2007-2013.

[17] See the Annex for the text of Articles 163ff EC Treaty

The European Commission also funds research into ethics, especially of new technologies, and it has proposed a couple of non-legislative measures, such as "action plans", a "Code of Conduct" or other guidelines for specific fields of research (e.g. the *Code of conduct for responsible nanosciences and nanotechnologies research*[18]).

1.4 Development Cooperation: Articles 177-181 EC Treaty[19]

In the field of development cooperation, the competence of the European Community is only complementary to the policies pursued by the Member States. Article 177 sets out that the European Community's development cooperation policy shall foster:

- *the sustainable economic and social development of the developing countries, and more particularly the most disadvantaged among them,*
- *the smooth and gradual integration of the developing countries into the world economy,*
- *the campaign against poverty in the developing countries* (Article 177 (1) EC Treaty).

Moreover, "*Community policy in this area shall contribute to the general objective of developing and consolidating democracy and the rule of law, and to that of respecting human rights and fundamental freedoms*" (Article 177 (2)).

Finally, Article 177 (3) requires that "*the Community and the Member States shall comply with the commitments and take account of the objectives they have approved in the context of the United Nations*".

[18] Commission Recommendation COM(2008)424), adopted on 7 February 2008)

[19] See the Annex for the text of Articles 177ff EC Treaty

It is primarily by the notion of "human rights" that the EU's policies can pose bioethical problems, in particular when it comes to the issue of so-called "reproductive health and rights" and abortion.

The Community's competence implies that the Council of Ministers and the European Parliament, by way of co-decision, "*adopt the measures necessary to further the objectives referred to in article 177*". To promote the objectives referred to in Article 177, the Council and the European Parliament can adopt multiannual programmes by way of the co-decision procedure according to Article 179.

One of the main instruments for development cooperation is currently *Regulation No. 1905 establishing a financing instrument for development cooperation* for the period 2007-2013 (see 1.5.B, p.59).

II. AREAS OUTSIDE THE COMPETENCE OF THE EU

In the areas where the Treaty does not confer competence to the EU, political initiatives can be taken by the different EU institutions to stimulate a political debate. In particular, when it comes to the European Parliament, it can issue "Resolutions" on different issues. In the past, some of them concerned bioethics.

For example, in 2002 the European Parliament adopted a *Resolution on Sexual and reproductive health and rights*[20]. This Resolution, although it "*notes that the legal or regulatory policy concerning reproductive health falls within the Member States' sphere of competence and that subsidiarity applies to these areas"* (paragraph 1), "*recommends that, in order to safeguard women's reproductive health and rights, abortion should be made legal, safe and accessible to all*" (paragraph 12).

Such Resolutions have no legal effect, yet they create a political climate.

[20] www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P5-TA-2002-0359+0+DOC+XML+V0//EN&language=EN

EU INSTITUTIONS INVOLVED IN BIOETHICS

I. EUROPEAN COMMISSION

The European Commission is the EU's executive arm. As a matter of principle, the European Commission is the only European institution that has legislative initiative; this relates also to the area of EU competences relevant to bioethics.

The role of the Commission is to act solely in the interest of the EU as a whole, as opposed to the Council of Ministers which consists of representatives of Member States, thus reflecting national interests. The President of the European Commission and all the other Commissioners are nominated by the Council; however, the appointment of the President and the Commission in its entirety has to be confirmed by the European Parliament.

1.1 Commissioners and their Directorates General

The College of the European Commission is currently composed of 27 Commissioners, one from each Member State, responsible for different areas of policy. The administrative structure of the European Commission consists of Directorates General – "DGs" - which cover specific policy fields. The DGs are politically directed by the relevant Commissioner. The DGs consist of services which are responsible *inter alia* for drafting legislative acts.

Within the European Commission, the following Commissioners are more likely to be dealing with bioethical issues:

Commissioner for Research and associated administrative services:

Directorate General for Research ("DG RTD"): DG Research is responsible for the proposals and the implementation of the EU's research programmes (see 1.4.B, p.48). Within DG Research, there is a unit specifically responsible for ethics, named "Science and Society".

Joint Research Centre (JRC): a research-based policy support organisation working for EU policy makers. The "*Institute for*

Prospective Technological Studies" is one of the (seven) institutes of the JRC. Its mission is to undertake forward-looking techno-economic analysis and monitor developments in science and technology, particularly in terms of their potential or projected policy implications.

Commissioner for Health and the Directorate General for Health & Consumers ("DG SANCO")

The DG is responsible for drafting the proposal for a *Directive on standards of quality and safety of human organs intended for transplantation* as well as an accompanying action plan; this proposal is subject to the legislative co-decision procedure in the European Parliament and the Council of Ministers (see 2.2, p.62).

Moreover, it is responsible for EU actions in the field of health and *inter alia* the "*Together for Health*" Health Programme 2008-2013[21] which aims at improving citizens' health security, promoting health and reducing health inequalities.

Commissioner for the Internal Market and Services and the Directorate General ("DG MARKT")

The Directorate General is responsible *inter alia* for EU legislation in the field of intellectual property.

Moreover, its main role is to coordinate the Commission's policy on the *European Single Market* and to seek the removal of unjustified obstacles to trade, in particular in the area of services and financial markets.

Commissioner for Enterprise and Industry and the Directorate General ("DG ENTR")

The Directorate General manages *inter alia* EU legislation in the field of pharmaceuticals. This includes legislation in the field of medicinal products for human use, in particular their marketing authorisation, testing, and distribution. The DG drafted the proposal

[21] For more info: http://ec.europa.eu/health/ph_programme/pgm2008_2013_en.htm

for *EU Regulation 1394/2007 on advanced therapies medicinal products* (see 1.1.D, p.39), for example.

Moreover, DG ENTR's mission is to ensure that EU policies contribute to the sustainable competitiveness of EU enterprises and facilitate job creation and sustainable economic growth. It has the task of ensuring that the single market for goods runs smoothly and of contributing to the implementation of the Lisbon strategy for growth and jobs.

1.2 Interservice Group on Ethics and EU Policies

This internal group of the European Commission, created in 2006, aims at allowing a better exchange of information and communication between the different Commission services in the field of ethics. It is coordinated by the Secretariat of the European Group on Ethics (see 1.3.A, p.20).

Its members are civil servants from different Directorates General of the European Commission.

According to its website[22], this platform on ethics and EU policies intends to achieve the following goals:

- to coordinate actions on ethics across Commission services;
- to allow a better exchange of information and communication between the Commission services in the fields of ethics and EU policies;
- to facilitate interactions and links between Commission services on ethics and EU policies as well as on specific initiatives being organised;
- to facilitate the coordination of contributions of EC Services with regard to initiatives on ethics of science carried out by International organisations, European institutions, and relevant third parties

[22] http://ec.europa.eu/european_group_ethics/platform/index_en.htm

1.3 Advisory bodies to the European Commission

A. European Group on Ethics in Science and New Technologies

In view of the need for advice on bioethics and research policy, the European Commission set up a number of advisory bodies, in particular the *European Group on Ethics in Science and New Technologies* (EGE) which is a consultative body nominated by the President of the European Commission.

The EGE was set up for its first mandate in 1997 by the European Commission to "*provide for independent and pluralist advice on ethical aspects of science and new technologies*" in connection with the preparation and implementation of Community legislation or policies. The group succeeded the *Group of Advisers on the Ethical Implications of Biotechnologies* (1991-1997).

During its first mandate (1998-2000) the EGE provided opinions on subjects such as human tissue banking, human embryo research, personal health data in the information society, doping in sport and human stem cell research[23]. Resulting from the composition of the EGE at that time, the opinions issued by the EGE in this mandate are quite liberal; they are used as a reference point in, for example, the European Commission's support of human embryonic stem cell research. To give an example: in opinion no. 12 dated 23 November 1998, the EGE considered an amendment tabled by the European Parliament to the then 5th Research Framework Programme; this amendment proposed to exclude from Community funding research projects that "*result in the destruction of human embryos*". Starting from the fact that the Member States take different approaches towards human embryo research, the EGE considered that "*The respect for different philosophical, moral or legal approaches and for diverse national culture is essential to the building of Europe. From an ethical point of view, the multicultural character of European society requires mutual tolerance...*" (point 2.5 of opinion no. 12). The EGE concluded that "*In the light of the aforementioned principles and specifications, the Group considers that according to*

[23] List of EGE opinions 1998-2000: http://ec.europa.eu/european_group_ethics/archive/1998_2000/avis_en.htm

the ethical dimension of the Community's Fifth Framework Programme Community funding should not a priori exclude human embryo research which is the object of different ethical choices in different countries." (point 2.8 of opinion no. 12).

During the second mandate 2001-2005, the EGE issued opinions on patenting of biotechnological inventions, clinical tests in developing countries, genetic testing in the workplace, cord blood banking and ICT (information and communication technology) implants in the human body[24]. Regarding the opinion on patenting, one member of the group, Prof. Virt (moral theologian, Vienna), issued a dissenting opinion against patents on human embryonic stem cells. Interestingly, the European Patent Office followed Prof. Virt's argument in its landmark decision to reject the patent applied for by Prof. Thomson on the creation of his human embryonic stem cell line (see below 1.1.A, p.33).

The current third mandate of the EGE will end with the term of office of the current Commission (end of 2009). The group issued opinions on nanomedicine, ethics review of human embryonic stem cell (hESC) research in the 7th Research Framework Programme, animal cloning for food supply, modern developments in agricultural technologies; it is currently finalising its opinion on "synthetic biology".

In its opinion no. 22 "*Recommendations on the ethical review of hESC FP7 research projects*"[25] the Group issued a preamble clarifying the scope of the opinion (which did not allow revisiting the ethical arguments in respect of human embryonic stem cell research set out in the opinions of previous EGE compositions):

"The EGE stressed that, as is the case in the European Union, there are divergent views within the Group on the moral legitimacy of research on human embryos and hESCs, ranging from objection to research involving the destruction of human embryos (which makes the full respect of dignity of the human embryo impossible), to a position allowing hESC research under certain conditions or on a broader basis.

[24] List of EGE opinions 2001-2005: http://ec.europa.eu/european_group_ethics/archive/2001_2005/avis_en.htm

[25] EGE, Opinion no. 22, full text see: http://ec.europa.eu/european_group_ethics/activities/docs/opinion_22_final_follow_up_en.pdf

The Group, however, acknowledged the political decision taken as the starting point for its Recommendations, but emphasised that the ethical dilemma regarding the moral status of the human embryo and its use in research still persists both within the EGE members and the EU. Therefore, the Group did not elaborate ethical arguments on hESC research as such, but worked on Recommendations for FP7 ethics review of hESC projects."

The call for proposals for membership in the fourth mandate of the EGE is expected by the end of 2009/beginning of 2010.

B. Advisory Groups for the Research Framework Programmes

Under the 6th Research Framework Programme, twelve Advisory Groups were created to give the Commission advice on overall strategy in developing the respective research activities, for example the *Advisory Group on Life Sciences, Genomics and Biotechnology for Health*, or the *Advisory Group on Science and Society*[26]. Members participated in their individual capacity and the Groups were managed by the relevant Commission services.

Advisory Groups have also been set up by the Commission for the 7th Framework Programme[27]. The membership and mandate of most of the groups were reviewed during autumn 2008. Currently, there are fourteen Advisory Groups, including one for "*Food Agriculture, Fisheries and Biotechnology*", one for "*Health*", and one for "*Nanosciences, Nanotechnologies*".

C. European Technology Platforms (ETPs)[28]

ETPs are a forum for stakeholders to define research and development priorities, timeframes and action plans on a number of strategically important issues where achieving Europe's future growth, competitiveness and sustainability objectives is dependent upon major research and technological advances in the medium to long term. ETPs are led by industry, and the Commission is of

[26] More information: http://cordis.europa.eu/fp6/eags.htm

[27] More information on the work of the Advisory Groups 2007-2008 is available at: http://ec.europa.eu/research/fp7/index_en.cfm?pg=eag-1st2years; for the work of the groups as of autumn 2008 please see: http://ec.europa.eu/research/fp7/index_en.cfm?pg=eag.

[28] http://cordis.europa.eu/technology-platforms/home_en.html

course not bound by their recommendations. Yet, without any doubt their recommendations have an important influence on the shaping of the European Commission's research policy.

Currently, there are 36 ETPs[29], covering the broad range from, for example, "*Aeronautics Research in Europe*", through "*European Biofuels Technology Platform*" to "*Nanotechnologies for medical applications*".

D. Joint Technology Initiatives according to Art. 171 EC Treaty

In accordance with Articles 171, 172 EC Treaty, the Council of Ministers, after consultation with the European Parliament, adopted on 23 December 2007 a *Council Regulation setting up the Innovative Medicines Initiative Joint Undertaking (IMIJU)*[30]. This IMIJU is a legal body created by the said Regulation; its objective is to improve the efficiency and effectiveness of the drug development process with the long-term aim that the pharmaceutical sector produce more effective and safer innovative medicines.

Joint Technology Initiatives are introduced in the 7th Research Framework Programme as a new way of realising public-private partnerships in research at European level. They aim for a better coordination of research efforts. The specific research programme "*Cooperation*" identified six areas where Joint Technology Initiatives could have particular relevance: hydrogen and fuel cells, aeronautics and air transport, innovative medicines, embedded computing systems, nanoelectronics and global monitoring for environment and security.

E. Ad-hoc-expert groups

Furthermore, the European Commission and its DGs regularly set up temporary ad-hoc-expert committees on different issues, for example:

[29] http://cordis.europa.eu/technology-platforms/individual_en.html

[30] Council Regulation EC 73/2008, 20 December 2007, full text: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:030:0038:0051:EN:PDF

- Expert Group on the legal, ethical and societal implications of genetic testing
  DG Research of the European Commission set up this multidisciplinary expert group to discuss the ethical, social and legal implications of genetic testing, and to propose actions. Members represented different interest groups: science, industry, patients, academics, lawyers and politicians; it was chaired by the former vice-chair of the European Parliament's Technology Assessment Office (STOA), Ms Eryl McNally. The group elaborated 25 recommendations[31] which were presented and discussed at a public conference in Brussels in May 2004.

- Expert Group "Foresighting the New Technology Wave"
  Also in 2004, DG Research set up a multidisciplinary group of 25 experts to deal with scientific and technological developments in view of the convergence of Nano-, Bio-, and Information technologies, and Cognitive sciences (NBIC). The **general objective** that guided the work of the group of experts[32] was *to assess the potential impact of Converging Technologies on the European Union (EU) competitiveness and societal fabric, and the potential response of the EU and Member States to that, understand the dynamics behind the "Converging Technologies agenda" in the US, while examining what possibilities exist for a European approach to exploiting the potential synergies across these technologies, and develop guidance for new research agendas, notably in the cognitive and social sciences.*

- High level group (Aho Group) "Creating an Innovative Europe"
  Following the Hampton Court Summit in 2005, Heads of State and Government decided to give higher priority to the key issues on which Europe needs to act to address the challenges of globalisation. First among these issues were research and innovation. The European Commission then asked a small group of four experts, chaired by former Prime Minister of Finland, Esko Aho, to assess the situation and make proposals to

[31] http://ec.europa.eu/research/conferences/2004/genetic/pdf/recommendations_en.pdf

[32] Further information and the group's final report is available at: http://cordis.europa.eu/foresight/ntw_expert_group.htm.

boost Europe's research and innovation performance. The group[33] issued its report on 20 January 2006.

- European Research Advisory Board (EURAB) – 2001-2007
  On the initiative of the then Commissioner for Research, Mr Busquin, the European Commission in 2001 appointed 45 members as a consultative committee (EURAB)[34] for the European Commission, to provide advice on the design and implementation of EU research policy. The 45 experts came from EU countries and beyond; they were nominated in a personal capacity and represented a range of academic and industrial backgrounds as well as other societal interests. In 2004, members were appointed for the second mandate of EURAB. EURAB delivered advice and opinions on specific issues either at the request of the European Commission or on its own initiative.

[33] http://ec.europa.eu/invest-in-research/action/2006_ahogroup_en.htm
[34] http://ec.europa.eu/research/eurab/index_en.html

II. EUROPEAN PARLIAMENT

The European Parliament (EP) is co-legislator, together with the Council of Ministers, in most legislative areas relating to legislative acts with bioethical relevance. Therefore it has significant influence on decisions with bioethical implications. It also adopts legally non-binding resolutions on a range of matters which nevertheless have political relevance. Evidently, the legislative powers of the Parliament and the Council are limited by the competencies conferred upon the European Community by the Member States.

The ***Rules of Procedure of the European Parliament***[35] are a useful instrument to understand the proceedings and the methods of the European Parliament.

2.1 Parliamentary Committees

The following Committees often discuss bioethical aspects of proposed EU-legislation:

Committee on Industry, Research and Energy (ITRE)[36] deals with matters relating to the EU's common commercial and industrial policy, matters relating to pharmaceutical and biotech companies as well as with matters relating to research policy;

Committee on Environment, Public Health and Food Safety (ENVI)[37] is responsible *inter alia* for public health, in particular programmes and specific actions in the field of public health and pharmaceutical and cosmetic products;

Committee on Legal Affairs (JURI)[38] is responsible *inter alia* for ethical questions related to new technologies.

[35] www.europarl.europa.eu/sides/getLastRules.do?language=EN&reference=TOC
[36] www.europarl.europa.eu/activities/committees/homeCom.do?language=EN&body=ITRE
[37] www.europarl.europa.eu/activities/committees/homeCom.do?language=EN&body=ENVI
[38] www.europarl.europa.eu/activities/committees/homeCom.do?language=EN&body=JURI

Committee for Women's Rights and Gender Equality (FEMM)[39] is responsible *inter alia* for the definition, promotion and protection of women's rights in the Union and with related Community measures and the promotion of women's rights in third countries.

"Temporary Commission on Human Genetics" (2001)

In December 2000, the EP set up a "Temporary Commission on Human Genetics and other new technologies of modern medicine". The aim was to draft a *Report on the ethical, legal, economic and social implications of human genetics*. The discussions both in the Committee as well as in the plenary were of a high quality, with many MEPs engaging in a substantive debate. Yet, these discussions also revealed that MEPs have fundamentally divergent views on many of these questions, and that these divisions go right across all political parties.

The resulting "Fiori Report" (named after the *rapporteur* Mr Fiori, EPP (Italy)) was adopted by the Committee (18 in favour, 13 against) on 6 November 2001. It was rejected, however, by the plenary of the European Parliament on 29 November 2001 by a large majority: 316 against, 37 in favour, 47 abstentions. This was basically due to the fact that the report aimed at covering a large range of bioethical issues, such as genetic testing, human embryo research, cloning, and patents. The cross-party coalitions within the Parliament, however, changed according to the different issues. Therefore, after the plenary voted on the individual issues, no majority of the European Parliament could identify with the content of the complete report. In particular, the report – after the vote on amendments – contained contradictory statements, for example: Whilst an amendment in favour of so-called therapeutic cloning was adopted, the report called on the Member States to set up laws against the production of human embryos by nuclear

[39] www.europarl.europa.eu/activities/committees/homeCom.do?language=EN&body=FEMM

cell transfer, a technique which is also required for therapeutic cloning.

Subsequent reports in the European Parliament, especially in the context of EU research funding, have deepened this division and entrenched positions which makes dialogue very difficult.

2.2 Political groups

The political groups play a vital role in the coordination of the work and of the voting of MEPs. Each political group has the right to a certain number of 'reports', in accordance with the results of the votes in the European elections, that means that they can choose the *rapporteur* for a given legislative or other proposal from among their political group. In each case, much will depend, clearly, on which individual MEP "receives" which report. The political groups which do not provide the *rapporteur* for a given report, decide on a *shadow-rapporteur* who coordinates the debate in the political group for that report. When it comes to negotiating compromise amendments, for example, the *rapporteur* will do this together with the 'shadows' from the other political groups.

Therefore, the *rapporteurs* and the 'shadows' are key contact persons in the European Parliament for a given Commission proposal.

2.3 Other networks in the European Parliament

There are many other networks of MEPs touching on bioethical issues within the EP, for example:

Scientific and technological options assessment unit (STOA)[40]

STOA is a body of the European Parliament aiming at assessing the impact of science and technology on EU policy. As technological and scientific advances are intimately linked with economic growth, the European Parliament considers it essential to investigate how to support scientific and technological innovation on the one hand and

[40] www.europarl.europa.eu/stoa/default_en.htm

to understand the impact of certain technologies on the other hand. The European Parliament defines its position on such issues normally through reports prepared by its Committees. However, if a Committee decides that it would be helpful to seek out external assessments on different scientific or technological options, they can draw on STOA.

STOA is composed of MEPs nominated by the European Parliament's Committees. The STOA panel is responsible for drawing up an annual workplan, after receiving proposals from various Committees.

STOA's work is carried out in partnership with external experts (such as research institutes, universities, consultancies etc); it increasingly focuses on round-table expert discussions and conferences to involve Members of the European Parliament and invited experts from EU institutions and institutions and NGOs outside the EU institutions to participate in a joint analysis of a given subject.

For example, STOA created a Working Group on "human enhancement" and organised a public workshop in the European Parliament on 24 February 2009[41].

Working Group on Bioethics of the EPP/ED group in the European Parliament

Working Group on Human Dignity in the European Parliament

Different Intergroups, that serve as informal cross-party forums so as to promote exchange across party lines and Committee membership on different issues, such as:

- *Health and Consumer Intergroup*[42]
- *Intergroup on the Welfare and conservation of animals*[43].

[41] www.europarl.europa.eu/stoa/events/workshop/20090224/default_en.htm
[42] intergroup.epha.org/rubrique.php3?id_rubrique=1
[43] www.eurogroupanimalwelfare.org/intergroup/intergroup.htm

III. COUNCIL OF MINISTERS

The Council of Ministers is co-legislator in the policy areas relating to bioethics. It represents the Member States, and its meetings are attended by a Minister (or a person with the rank of Minister) from each of the EU's national governments. The role of the President of the Council is rotated between the Member States every 6 months (known as the 'Presidency'); it is then the Minister from that Member State who is responsible for setting the agenda and chairing the meetings.

As an institution, there is one Council of Ministers, but it meets in different configurations depending on the subjects being examined. Most issues with bioethics relevance are discussed in the following Council configurations:

Competitiveness Council

The Competitiveness Council was created in June 2002 through the merging of three previous configurations (Internal Market, Industry and Research); the merging was aimed at a more coherent and better coordinated handling of matters related to the EU's competitiveness. Depending on the items on the agenda, this formation is composed of Ministers responsible for areas such as European Affairs, Industry, Research, etc. It meets about five or six times a year.

Employment, Social Policy, Health and Consumer Affairs Council (EPSCO)

The EPSCO Council is composed of employment, social protection, consumer protection, health and equal opportunities Ministers, who meet around four times a year.

Agriculture and Fisheries

It is one of the Council's oldest configurations; it brings together the Ministers for Agriculture and Fisheries who meet about once a month.

Most decisions of the Council of Ministers which deal with bioethical issues require a ***qualified majority***[44]. Even if unanimity is not required, the praxis of negotiation in the Council is such that the Presidency of the Council tries to negotiate a consensus with which all can agree. That means that if a Member State engages early in the debate, and uses good arguments and negotiation skills at the same time including a coalition of other Member States, chances are very high that this Member State can significantly influence the end result.

The permanent structure of the meetings of the Council of Ministers is provided by the General Secretariat of the Council - the Secretary General of the Council being the head of the General Secretariat.

The work of the Council of Ministers is prepared and coordinated by the ambassadors and civil servants of the Permanent Representations of the different Member States in Brussels on two levels:

- The first level is the discussion of a given legislative (or other) proposal of the European Commission in one of the many ***Council Working Groups*** (one on research, another on health etc). Members of these Council Working Groups are representatives of the Member States, either a staff member of the Permanent Representation of each Member State or an official from the Ministry responsible in the capital of that Member State. The Group is chaired by the representative of the Member State currently holding the Presidency of the EU; thus the chairmanship rotates in line with the presidency of the EU.

[44] Qualified majority is obtained with a minimum of 255 votes out of the total of 345 (73,9%) plus a majority of Member States – or, alternatively, a majority representing 62% of the EU's population. Under qualified majority voting, different Member States have different voting weights based on their population. For example, a vote by Germany or France carries 29 votes out of the total 345, whereas a vote by Cyprus or Latvia carries only four votes. The complete list of voting weights is the following:
29 votes: France, Germany, Italy, and the United Kingdom,
27 votes: Spain and Poland,
14 votes: Romania,
13 votes: The Netherlands,
12 votes: Belgium, the Czech Republic, Greece, Hungary, and Portugal,
10 votes: Austria, Bulgaria, and Sweden,
7 votes: Denmark, Finland, Ireland, Lithuania, and Slovakia,
4 votes: Cyprus, Estonia, Latvia, Luxembourg, and Slovenia,
3 votes: Malta.

- On the next level, the proposal is discussed by the Permanent Representatives or their Representatives in what is called ***"COREPER 1" and "COREPER 2"***. COREPER is the French acronym for "*Committee of the Permanent Representatives*". *COREPER 2* consists of the Permanent Representatives of the Member States and deals largely with general political, financial and foreign policy issues. COREPER 1 brings together the Deputy-Permanent Representatives and covers largely social and economic issues; it prepares the work *inter alia* for the above-mentioned Council configurations "*Competitiveness*" and "*Employment, Social Policy, Health and Consumer Affairs*". The legal basis of the Committee is laid down in Article 207 EC Treaty. For most issues of bioethical relevance, *COREPER 1* is the relevant Committee.

  On both of these levels, the Permanent Representations generally receive their instructions from the competent Ministry responsible in the government of each Member State.

- The final level is the meeting of the ***Council of Ministers*** themselves (in its different configurations); if the Council Working Group or COREPER has reached a consensus on a given proposal, the Council of Ministers formally adopts the proposal without discussion. In other cases, the Ministers will have a debate and will negotiate an agreement themselves.

For some items of legislation, the Council of Ministers does not confer the implementing responsibility entirely to the European Commission. For example, whilst the European Commission is in principle responsible for the implementation of the EU's research programmes, a special "regulatory procedure" applies for the *approval of the funding of* (research) *actions involving the use of human embryos and human embryonic stem cells* (Article 7 (3) of the first specific research programme – see 1.4.B, p.50).

The Regulatory Committee consists of representatives of the 27 Member States, and thus the Member States are directly involved in the funding decision (for further information see 1.4.B, p.50).

EU LEGISLATION AND OTHER MEASURES

I. OVERVIEW ON MAJOR ITEMS OF EU LEGISLATION IN FORCE

1.1 Legislation based on Article 95 EC Treaty (Internal Market)

A. Directive 98/44/EC on the legal protection of biotechnological inventions

One of the earliest debates on bioethics arose in the context of the negotiations for ***Directive 98/44/EC on the legal protection of biotechnological inventions*** of 6 July 1998. This Directive, based on Article 100a (predecessor of Article 95 of the EC Treaty), was aimed at facilitating the common market. However, as biological inventions were its subject, it posed, *inter alia*, bioethical questions: What about patents on human genes, and what about uses of human embryos in the field of biotechnological inventions?

First Commission proposal (1988)

The Commission had already proposed a first legislative proposal for a *Directive on the legal protection of biotechnological inventions* in 1988[45]. In this first legislative proposal, no reference was made to the ethical dimension of the draft directive. Rather, the aim of the European Commission proposal was to extend patent protection on living materials in general. However, in the debates in the European Parliament during first reading, the Parliament insisted that there needed to be safeguards introduced in order to ensure that, for example, the human body and its parts would not be subject to patents, and also that a general clause should be introduced forbidding inventions contrary to public order and public morality. In particular, processes to modify the genetic identity of the human body should be prohibited. The Council of Ministers accepted some but not all of the amendments requested by the European Parliament.

[45] Proposal for a Council Directive on the legal protection of biotechnological inventions, COM (1988) 496

Therefore, in second reading, the European Parliament reaffirmed *inter alia* the principle of a complete ban on patenting the human body or elements of the human body. The Council of Ministers had proposed to add "as such"; this was rejected by the European Parliament because it could reduce the scope of this prohibition. In the eyes of the *rapporteur* (Mr Rothley, PSE) the words "as such" could be interpreted as follows: that proteins, enzymes and genes, for example, were only excluded from patenting as long as they were in the human body. In the subsequent negotiations of the Conciliation Committee (between the Parliament and the Council), difficult negotiations took place to find a compromise. However, even although the *rapporteur* supported the compromise proposed by the Conciliation Committee, the European Parliament rejected – by 240 votes to 188, with 23 abstentions – the draft *Directive on the legal protection of biotechnological inventions*.

Second Commission proposal (1995)

In 1995, the European Commission presented a new proposal for a Directive on the legal protection of biotechnological inventions[46]. *Inter alia*, it made a clear distinction between discovery and invention (only the latter being patentable under certain conditions). In view of patents on elements of human origin, the draft Directive proposed:

> *Article 3:*
>
> *1. The human body and its elements in their natural state shall not be considered patentable inventions.*
>
> *2. Notwithstanding paragraph 1, the subject of an invention capable of industrial application which relates to an element isolated from the human body or otherwise produced by means of a technical process shall be patentable, even if the structure of that element is identical to that of a natural element.*

[46] Official Journal L 213, 13ff, 6 July 1998, full text: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:213:0013:0021:EN:PDF

Also, a general clause on public policy and morality was proposed:

> *Article 9:*
>
> *1. Inventions shall be considered unpatentable where exploitation would be contrary to public policy or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.*
>
> *2. On the basis of paragraph 1, the following shall be considered unpatentable:*
>
> *a. methods of human treatment involving germ line gene therapy;*
>
> *b. processes for modifying the genetic identity of animals which are likely to cause them suffering or physical handicaps without any substantial benefit to man or animal, and also animals resulting from such processes, whenever the suffering or physical handicaps inflicted on the animals concerned are disproportionate to the objective pursued.*

Again, the European Parliament insisted that the ethical dimension be strengthened. In first reading it adopted, by 370 votes to 113 with 19 abstentions, the report by Mr Rothley (PSE) which excluded *inter alia* the following from patenting: the human body, at any stage in its formation or development, or the mere discovery of one of its elements, including the sequence or partial sequence of a gene; cloning of human beings, methods in which human embryos are used.

In the course of the debate, the European Parliament and the Council of Ministers agreed that uses of human embryos for industrial or commercial purposes and processes for cloning human beings should be excluded from patenting. The following Articles 5 and 6 of the Directive reflect the agreed compromise:

> *Article 5*
>
> *1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.*
>
> *2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.*
>
> *3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.*
>
> *Article 6*
>
> *1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.*
>
> *2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:*
>
> *(a) processes for cloning human beings;*
>
> *(b) processes for modifying the germ line genetic identity of human beings;*
>
> *(c) uses of human embryos for industrial or commercial purposes;*
>
> *(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.*

Also, the Directive mandates the European Group on Ethics to evaluate ethical aspects of biotechnology (see 1.3.A, p.20):

> *Article 7: The Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology.*

Moreover, the Directive obliges the European Commission in Article 16c) to present an annual report "on the development and implications of patent law in the field of biotechnology and genetic engineering"

Patenting of human embryonic stem cells?

At that time, the question of patenting human embryonic stem cell lines had not been discussed, because this technique was not yet available (the first human embryonic stem cell line was only created in the same year as the Directive was adopted). Therefore, after the adoption of the Directive it was a matter of dispute whether human

embryonic stem cell lines were patentable or not according to the Directive.

The European Commission explicitly did not take a position on this question: in its annual report (COM (2005)312 final) dated 14 July 2005, it stated that "*there is no immediate answer to the question of the patentability of embryonic pluripotent stem cells and indeed at this stage it would appear premature to come to a definitive conclusion*". The European Group on Ethics, however, the advisory body to the President of the European Commission, considered in its opinion no 16 dated 7 May 2002: "*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. Moreover, the Group considers that it would be contrary to the EU choices as expressed by the 1998 EU Directive on patenting*." (paragraph 2.1 of opinion no. 18 of the EGE). However, one member of the EGE (Prof. Günter Virt, Austria) issued a dissenting opinion, stating that the patentability of human embryonic stem cells was contrary to the Directive.

The European Parliament, in a Resolution adopted on 26 October 2005 (see 3.2, p.70), clearly supported the position of this dissenting opinion, stating "*that the creation of human embryonic stem cells implies the destruction of human embryos and that therefore the patenting of procedures involving human embryonic stem cells or cells that are grown from human embryonic stem cells is a violation of Article 6 (2)(c) of the Directive*". Furthermore, the European Parliament requested that, in view of patents on human DNA, the "*scope of the patent should be limited to this concrete application*". It is noteworthy that the European Parliament in this Resolution adopted by a majority a paragraph rejecting "*research on human embryos, which destroys the embryo*".

The European Patent Office (EPO) in Munich, an independent intergovernmental European organisation, incorporated the wording of Directive 98/44/EC in its own rules. After it had granted a patent to Wisconsin Alumni Research Foundation (WARF), which also

included a patent on a human embryonic stem cell line, many organisations and individuals lodged appeals against the said patent. The COMECE Secretariat participated in the discussions by way of a (public) "*amicus curiae-letter*" sent to the Enlarged Board of Appeal of the European Patent Office. It argued that the Directive ruled out any patents not only on human embryos but also on human embryonic stem cells. On 25 November 2008, the final (legally binding) decision was taken by the Enlarged Board of Appeal of the EPO. It refused WARF's patent application insofar as it implied human embryonic stem cells, deciding that it fell within the exception to patentability under Article 53(a)2 and Rule 28(c) EPC. Whilst inventions which can only be exploited by the destruction of human embryos were thus held to be unpatentable, the Enlarged Board of Appeal emphasised that this decision does not concern the more general question of human stem cell patentability.

The implications of this decision for European patent practice are still under discussion.

B. Directive 98/79/EC on in vitro diagnostic medical devices

In the same year as the adoption of the Biopatenting Directive, the European Parliament and the Council of Ministers adopted on 27 October 1998 a ***Directive 98/79/EC on in vitro diagnostic medical devices***[47]. This Directive also covers the use of human tissues. The legal basis of this Directive was Article 100a (the predecessor of Article 95).

In view of bioethical decisions of Member States, the principle of subsidiarity is clearly reflected in recital 33 which reads: "*Whereas, in view of the need to protect the integrity of the human person during the sampling, collection and use of substances derived from the human body, it is appropriate to apply the principles laid down in the Convention of the Council of Europe for the protection of human rights and dignity of the human being with regard to the application of biology and medicine;* ***whereas, furthermore, national regulations relating to ethics continue to apply****;"*

[47] Official Journal L 333, 1ff, 27 October 1998, full text: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:331:0001:0037:EN:PDF

Thus, the Directive reflects the view that the EU only provides "minimum standards", and that the Member States are free to make their "ethical" decisions.

The "minimum standards" refer mainly to the principles laid down by the Oviedo Convention (see above part 1).

C. Directive 2001/83/EC on the Community code relating to medicinal products for human use

This Directive[48], adopted by the European Parliament and the Council of Ministers on 6 November 2001, applies to industrially produced medicinal products for human use which are intended to be marketed in Member States. It aims at setting common standards for the authorisation of such products. Also, it provides for facilitated market authorisation in a Member State, if a given product has been authorised by the competent authority in another Member State.

However, Article 4 paragraph 4 provided for the possibility of Member States to prohibit or restrict the sale, supply or use of contraceptives and abortifacients; also, the Member States are free to decide whether or not medicinal products are included in the scope of national health insurance schemes (Article 4 (3)).

D. Regulation (EC) No 1394/2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004

The European Parliament and the Council of Ministers adopted on 13 November 2007 a "***Regulation (EC) No 1394/2007 on advanced therapy medicinal products*** and ***amending Directive 2001/83/EC and Regulation (EC) No 726/2004***"[49], based on Article 95 of the EC Treaty. The Regulation introduces an EU-wide decision on the market authorisation of such products. Scientific advances in biology, biotechnology and medicine give grounds for expecting the development of advanced therapies on the basis of gene and cell

[48] Official Journal L 311/67ff, 28 November 2001; full text: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:EN:PDF

[49] Official Journal L324/121ff, 10 December 2007; full text: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:324:0121:0137:EN:PDF

therapies as well as tissue engineering. All of these are based on complex and highly innovative manufacturing processes for which specific rules and expertise were lacking.[50]

Main elements of the Regulation:

- a centralised marketing authorisation procedure, in order to benefit from the pooling of expertise at European level and direct access to the EU market

- a new, multidisciplinary expert *Committee for Advanced Therapies*, within the European Medicines Agency (EMEA), to assess advanced therapy products and monitor scientific developments in the field

- technical requirements adapted to the particular characteristics of these products

The dossier is very technical because the Regulation supplements existing EU legislation: In respect of some of the "advanced therapies" - gene therapy and somatic cell therapy - there has already been an EU authorisation since 2004 (see 1.3, p.46: *Regulation No. 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency*).

Bioethical dimension:

This Regulation is to be welcomed insofar as it may foster the development of drugs and new therapies; also it may contribute to better competitiveness for European pharmaceutical companies.

However, there are a number of serious ethical concerns:

- Regarding the ***principle of non-commercialisation of the human body:***

- The principle of non-commercialisation is a major ethical demand in the case of advanced therapies (which frequently depend on the

[50] A report by the Institute for Prospective Technological Studies at the EU Joint Research Centre from the year 2004 came to the conclusion that the lack of such an EU-wide authorisation process is hampering the growth of a nascent knowledge-based industry (www.jrc/es/home/toolbar/whats_new.html).

use human cells and tissue), and is based on the prohibition of ***the commercialisation of the human body and its parts*** enshrined in the EU Charter of Fundamental Rights and in the Oviedo Convention. In the draft Regulation reference is made to Regulation 2004/23/EC whereby Member States are to "strive" to ensure voluntary and unpaid donations of tissue and cells.

As the chosen legal instrument is a directly binding Regulation, this provision is, however, not sufficient. Because of the legal force of a Regulation (as opposed to a Directive) it would have been adequate to introduce uniform and binding rules enforcing the principle of non-commercialisation. In view of the legal basis (Article 95 EC Treaty), one can also argue that this is all the more important because different rules in the Member States on "payment" for cell and tissue donations could distort competition and therefore the internal market, thus contradicting the purpose of Article 95 EC Treaty.

- An additional ethical problem concerns the prohibition on ***interference with the human germ line***, i.e. the alteration of egg and sperm cells having impact on future generations. Both the Oviedo Convention of the Council of Europe and the FP7, the Biotechnology Regulation and the Regulation on clinical tests disapprove of such interventions

- In the future, "advanced therapies" may be developed on the basis of ethically contentious procedures, such as the use of human embryonic stem cells. Therefore, the following ethical problems could arise:

  - The authorisation of possible future advanced therapy products created on the basis of certain tissues and cells (e.g. ***products derived from human embryos or embryonic stem cells***).

  - The authorisation of possible future advanced therapy products containing animal *and* human cells, thus ***not excluding the use of chimeric or hybrid entities***.

The *European Commission's* proposal for addressing the problem of subsidiarity (and of respecting the Member States' decisions in view of the use of ethically contentious tissues and cells) is by Article 28 (3) of the Regulation. This provision aims at safeguarding the powers of Member States to prohibit or restrict the use of any specific type of human or animal cells (e.g. human embryonic stem cells). However, it is uncertain whether this provision is in line with the legal basis of the Regulation (Article 95 EC Treaty); it is possible that the European Court of Justice (who would have the final word in the event of a dispute), would find that this provision would be in contradiction with the legal basis of the Regulation.

For this reason, the Legal Affairs Committee of the *European Parliament* had proposed in its opinion[51] to restrict the scope of the Regulation, by including a new Article 1a: "*This Regulation shall not apply to any advanced therapy medicinal products that contain or are derived from human embryonic and foetal cells, primordial germ cells and cells derived from those cells*". The plenary session of the European Parliament voted in first reading on 25 April 2007. However, the proposals to improve the ethical framework of the Regulation were not adopted.

The *Council of Ministers*, at the meeting of Health Ministers on 31 May 2007 in Brussels, agreed unanimously to accept the amendments of the European Parliament in first reading and not to propose further modifications (for example regarding ethical issues). The Regulation was formally adopted by the Council of Ministers during its meeting on 30 October 2007 and entered into force on 30 December 2008.

<u>Ethical provisions in the adopted Regulation</u>

In the Regulation as finally adopted, the following provisions apply with regard to ethical issues:

- recital 7: *The regulation of advanced therapy medicinal products at Community level should not interfere with decisions made by Member States on whether to allow the use of any specific type of human cells,*

[51] www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-374.450+02+DOC+PDF+V0//EN&language=EN

such as embryonic stem cells, or animal cells. It should also not affect the application of national legislation prohibiting or restricting the sale, supply or use of medicinal products containing, consisting of or derived from these cells.

- recital 8: *This Regulation respects the fundamental rights and observes the principles reflected in the Charter of Fundamental Rights of the European Union and also takes into account the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine.*

- recital 15: *As regards the donation of human cells or tissues, principles such as the anonymity of both donor and recipient, altruism of the donor and solidarity between donor and recipient should be respected. As a matter of principle, human cells or tissues contained in advanced therapy medicinal products should be procured from voluntary and unpaid donation. Member States should be urged to take all necessary steps to encourage a strong public and non-profit sector involvement in the procurement of human cells or tissues, as voluntary and unpaid cell and tissue donations may contribute to high safety standards for cells and tissues and therefore to the protection of human health.*

For the donation of tissues and cells, and that implies the question of the commercialisation of human tissues and cells, the Regulation refers to Directive 2004/23/EC which states in Article 12: *"Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells. Donors may receive compensation which is strictly limited to making good the expenses and inconveniences related to the donation. In that case, Member States define the conditions under which compensation may be granted".*

Finally, Article 28 (3) of the Regulation contains an important provision regarding the powers of Member States to prohibit or restrict the use of any specific type of human or animal cells (for example human embryonic stem cells): in amending Directive 2001/83/EC the following paragraph 5 is added: "*This Directive and all Regulations referred to therein shall not affect the application of national legislation prohibiting or restricting the use of any specific type of human or animal cells, or the sale, supply or use of medicinal products containing, consisting of or derived from these cells, on grounds not dealt with in the aforementioned Community legislation. The Member States shall*

communicate the national legislation concerned to the Commission. The Commission shall make this information publicly available in a register."

<u>Brief evaluation:</u>

In order to be able to choose a Regulation as the legal instrument for this legal act, the legal base had to be Article 95 of the EC Treaty. In contrast to a Directive (which requires a national law transposing the Directive into national law), a Regulation is directly applicable in all Member States. The European Commission considered that for an EU-wide authorisation procedure, it would be important to have a uniform legislative instrument.

With regard to ethical issues, it is highly regrettable that the scope of the Regulation was not restricted in order to exclude certain ethically problematic possible future products from the application of the Regulation. Instead, the EU institutions introduced the possibility of an "opt-out" with regard to ethically sensitive human cells. This can of course be seen as an implicit incentive to pursue all kinds of research, even with ethically contentious methods.

Technically, the opt-out is provided by Article 28 (3) which modifies Directive 2001/83/EC as mentioned above. From a legal point of view, this provision lacks clarity, as the modified Directive, which constitutes the weaker legal basis, stipulates that "*the Directive* ***and all Regulations referred to therein*** *shall not affect the application of national legislation prohibiting or restricting the use of any specific type of human or animal cells….*".

In the event of dispute, and taking into consideration the "opt-out" provided for in Article 28 paragraph 3, the matter will be decided by the European Court of Justice. It is an open question whether the European Court of Justice would accept this derogation from the aim of the legal basis (Article 95 EC Treaty), which is to establish a *full harmonisation* of the market. Also for this reason the Regulation can be criticised for being based exclusively on Article 95, and not on Article 152 EC Treaty.

1.2 Legislation based on Article 152 EC Treaty (Health)

In the area of EU competence for public health, a couple of Directives were adopted which were based on Article 152 of the EC Treaty, in particular:

Directive 2004/23/EC[52] *on setting standards of quality and safety for the donation, procurement, testing, processing of human tissues and cells*

This Directive concerns the donation/procurement etc of human tissues and cells intended for application to human beings. Given the divergent positions of the EU Member States, this could in some Member States include human germ cells and human embryonic stem cells, for example.

In order to observe the principle of subsidiarity, in this context, the Directive provides in Article 4 (3): "*This Directive does not affect the decisions of the Member States prohibiting the donation (etc) of any specific type of human tissues or cells or cells from any specific source, including where those decisions also concern imports of the same type of human tissues or cells"*. That means, only if a Member States allows for the use of such cells, will their donation etc be subject to the rules of the Directive.

Another bioethical question of this Directive relates to the principle of non-commercialisation of the human body and its parts. Article 12 states: *"Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells. Donors may receive compensation which is strictly limited to making good the expenses and inconveniences related to the donation. In that case, Member States define the conditions under which compensation may be granted"*. It has to be appreciated that compensation is strictly limited to making good expenses and inconveniences, thus excluding a "payment"; however, the term "inconveniences" is very unspecific and therefore is in danger of being interpreted in a very broad way,

[52] Official Journal L 102/48ff, 7 April 2004; full text: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:102:0048:0058:EN:PDF

rendering void the principle of unpaid donation. As the Directive requires transposition into national laws, this unspecific wording leaves substantial room for Member States to interpret the Directive in either direction with regard to the principle of non-commercialisation.

Misuse in national debates

The implementation of this Directive by the Belgian legislature in December 2008 reveals a common experience in how Member States can make use of EU Directives (which require transposition into national laws). In this case, the Belgian Parliament adopted – unanimously – a law that treated human tissues and human *embryos* on the same level. Several Members of the Belgian Parliament are reported to have said that there was nothing they could do about it, because the EU Directive required this (which is not in fact the case).

This is just an example on how a national legislature can use (and misuse) a given EU Directive in the national debate, and how fatal can be the lack of detailed knowledge about the EU Directive in question.

It may also be remembered that all national governments are involved in the adoption of EU legislation; even if in principle a qualified majority of Member States is sufficient: in practice the Council of Ministers arrives at a unanimous decision in most cases. In any event, if a national government is well informed and skilled in EU negotiations, it can significantly influence the debates on the EU legislation in question. It can also happen, however, that a national government may take advantage of the EU debates in order to promote a certain item of EU legislation which it would not be able or willing to promote openly at the national level.

1.3 Legislation based on Article 152 and Article 95

Sometimes, an item of EU legislation is based both on Article 152 (public health) and Article 95 (internal market); this fact reflects the tension between, on the one hand, the wish to create an industry-friendly common market in the EU and to provide European patients

as quickly and effectively as possible with new products and therapies and, on the other hand, Member State competence in respect of their health systems as well as the question of differing bioethical standards. It also reveals a tension between the free market and the principle of subsidiarity and, in particular, respect for different (bio)ethical choices of Member States.

Regulation EC No 726/2004[53] *laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing the European Medicines Agency*

The European Medicines Agency was established in the year 2004 by the adoption of *Regulation EC No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing the European Medicines Agency*. The aim was to lay down Community procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human and veterinary use. With this Regulation, the EU introduces a centralised authorisation procedure for high-technology medicinal products in order to ensure a high level of scientific evaluation; this was considered to be particularly important in the context of the emergence of new therapies, such as gene therapy and associated cell therapies (recital 7 of the Regulation).

The evaluation of new medicinal products for human use is prepared by a new "*Committee for Medicinal products for human use*", which is part of the European Medicines Agency. Each Member State appoints one member and one alternate of the Management Board of the EMEA and one member and one alternate to the Committee. The members of each Committee may be accompanied by experts in the specific scientific or technical fields.

The authorisation decision should be taken on the basis of scientific criteria concerning the quality, safety and efficacy of the medicinal product concerned. The marketing authorisation may be refused if a)

[53] Official Journal L 136/1ff, 30 April 2004; eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:EN:PDF

the applicant has not properly or sufficiently demonstrated the quality, safety or efficacy of the medicinal product or if b) the particulars provided are incorrect.

Whilst it clearly represents an advantage to pool scientific expertise in the evaluation of new medicinal products and their scientific merits, the question arose as to how the divergent ethical positions of Member States are to be respected when it comes to ethically contentious products, such as the so-called "morning-after pill", e.g. RU 286. For this, Article 13 (1) of the Regulation refers to Article 4 (4) of Directive 2001/83/EC (see above 4.1.1.3) which clarifies that Member States are free to prohibit or restrict the sale, supply or use of contraceptives or abortifacients.

1.4 EU measures based on Articles 163-173 EC Treaty (Research)

A. EU Research Policy

The next main area concerns EU Research Policy. In this respect, the internationality of research, worldwide competitiveness and the importance of excellence in research for the well-being of the European economy is obvious. It may be recalled that there is no competence for the European Community to "legislate" research policy, but the EC Treaty contains *inter alia* in Article 166 the competence to set up a multi-annual EU Research Framework Programme outlining the EU research fields funded by EC funds. In this context it may be mentioned that the Charter of Fundamental Rights, as do most national constitutions, contains a right to "freedom of research".

Research policy is considered by the EU as a main contributor to the Lisbon Strategy, to improve EU's competitiveness. The ***Lisbon Strategy*** was adopted by the Heads of State and Government at the Lisbon European Council in 2000, and it contains a commitment to bring about economic, social and environmental renewal in the EU. They set the EU the goal of becoming by 2010 "*the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and greater social cohesion*". One element for achieving this goal was the project

for creating a European Research Area, proposed by the Commission in its Communication ***"Towards a European Research Area"***[54]. The Council of Ministers reacted by adopting a Council Resolution on 15 June 2000[55].

At the Barcelona European Council in 2002, the Heads of State and Government reviewed the progress towards the Lisbon goal, and agreed that investment in European research and development must be increased with the aim of approaching 3% of the GDP by 2010 (as opposed to 1.9% in 2000). In September 2002, the Commission adopted a Communication ***"More research for Europe – Towards 3% of GDP"***[56], followed by a Communication dated 30 April 2003: ***"Investing in research: an action plan for Europe"***[57].

A further milestone in the development of EU research policy was the launch of the ***European Research Council***: On 27/28 February 2007, it was launched at an inaugural conference in Berlin hosted by the German EU Presidency and organised jointly by the German Research Foundation (DFG) and the European Commission. The European Research Council is in charge of implementing a part of the current 7th EU Research Framework Programme (the specific programme "*Ideas*"; see 1.4.B, p.50).

On 4 April 2007, the European Commission adopted a "***Green Paper on the European Research Area: New Perspectives***"[58], which proposed for debate a vision of the European Research Area based on six dimensions: realising a single labour market for researchers; developing world-class research infrastructures; strengthening research institutions; sharing knowledge; optimising research programmes and priorities; and opening to the world through international cooperation in Science and Technology. On the basis of

[54] Commission Communication, 18 January 2000 (COM(2000)6); full text: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0006:FIN:EN:PDF

[55] Council Resolution of 15 June 2000 on establishing a European area of research and innovation, OJ C 205/1, 19 July 2000; full text: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2000:205:0001:0003:EN:PDF

[56] Commission Communication, 11 September 2002 (COM(2002)499), full text: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0499:FIN:EN:PDF

[57] Commission Communication, 4 June 2003, (COM(2003)226 final/2); full text: ec.europa.eu/invest-in-research/pdf/226/en.pdf

[58] COM (2007)161 final, 4 April 2007, full text: ec.europa.eu/research/era/pdf/era_gp_final_en.pdf

the Green Paper, the European Commission opened a broad public consultation to which the Secretariat of COMECE contributed[59].

B. EU Research Framework Programmes

The *multiannual research framework programmes* foreseen in Article 166 of the EC Treaty, are the EU's main tool for shaping EU research policy. It covers the whole range of research, from medical research to security, from space to telecommunications etc. As regards ethics, it is evident that any EU funding for ethically contentious research is a political signal and may be considered as providing a framework of research which can or should be considered "ethical".

7th Framework Programme for Research and Technological Development (FP7)

This current programme[60] covers a 7 year-period from 2007-2013 with an overall budget of around 50 billion Euros. The money is for the most part spent on grants to research actors all over Europe and beyond, in order to co-finance research and technological development projects. Grants are determined on the basis of "calls for proposals" and a peer review process. The majority of these projects must be transnational: research projects and must be carried out by consortia which include participants from different European (and other) countries. With the creation of the new "European Research Council", research projects of individual researchers or research teams can also be supported.

FP7 is structured in four so-called "specific programmes":

- *Cooperation* programme: This is the core of FP7, representing roughly two-thirds of the overall budget. It fosters collaborative research across Europe and other partner countries through

[59] ec.europa.eu/research/era/pdf/commission-of-the-bishops-conferences-of-the-european-community-comece_en.pdf

[60] Text FP7 (OJ L 412/1 of 30/12/2006): eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:412:0001:0041:EN:PDF; Further info: "FP7 in brief": ec.europa.eu/research/fp7/pdf/fp7-inbrief_en.pdf; "FP7 – tomorrow's answers start today": ec.europa.eu/research/fp7/pdf/fp7-factsheets_en.pdf

projects by transnational consortia of industry and academia in the following ten key ***thematic areas***: health, food/agriculture/fisheries/biotechnology, information and communication technologies, nanosciences, energy, environment (including climate change), transport, socio-economic sciences and the humanities, space, security.

The implementation of the Specific Programme "*Cooperation*" is managed by the European Commission in annual "Work Programmes" for each thematic area; they cover a period of 1-3 years and detail the areas that will be funded within each thematic area. These work programmes include the schedule of "calls for proposals" published during the year.

- *Ideas* programme: It is not linked to the above mentioned thematic priorities, and it is not managed by the European Commission, but by the European Research Council (ERC). It covers research in any area of science or technologies, aiming at "frontier research"; projects are selected solely on the basis of "scientific excellence".
- *People* programme: It provides support for researcher mobility and career development.
- *Capacities* programme: It aims at strengthening the research capacities by supporting *inter alia* research infrastructures, regions of knowledge and "science in society".

Nuclear research is funded under the ***7th Framework Programme of the European Atomic Energy Community (Euratom) for nuclear research and training activities (2007-2011)***; Euratom is legally separated from the European Community (EC) and has its own Framework Research Programme managed by the common Community institutions. The Programme with a budget of 2 751 million EUR runs from 2007-2011.

Bioethical debate in FP7

In the fields of biotechnology and medical research in particular, the question of ethical limits has been the subject of deep and impassioned debate in the EU institutions.

The European Commission's position has been

- that decisions of Member States not to proceed with a particular research path on ethical grounds (such as the use of human embryonic stem cells) should be "respected", and
- that nevertheless the EU as a whole should not completely withdraw from what it considers important research areas.

However, the Commission insisted that "fundamental ethical principles" must be respected without, however, specifying the content of these principles. In practice, the European Commission follows the line of the Oviedo Convention of the Council of Europe which excludes the creation of human embryos for research purposes and all forms of human cloning.

In the finally adopted Article 6 of FP7[61], the "ethical principles" for EU-funded research are laid down, which excludes the following research activities from EU funding:

- the creation of human embryos for research, including therapeutic cloning,
- the modification of the genetic heritage of human beings if these are heritable
- human reproductive cloning.

[61] Article 6 of FP7 (Ethical principles) reads as follows (emphasis added):
1. All the research activities carried out under the Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles.
2. ***The following fields of research shall not be financed under this Framework Programme:***
- research activity aiming at human cloning for reproductive purposes,
- research activity intended to modify the genetic heritage of human beings which could make such changes heritable,
- research activities 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.
3. Research on human stem cells, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member State(s) involved. Any application for financing for research on human embryonic stem cells shall include, as appropriate, details of licensing and control measures that will be taken by the competent authorities of the Member States as well as details of the ethical approval(s) that will be provided. As regards the derivation of human embryonic stem cells, institutions, organisations and researchers shall be subject to strict licensing and control in accordance with the legal framework of the Member State(s) involved.
4. The fields of research set out above shall be reviewed for the second phase of this programme (2010-2013) in the light of scientific advances."

In contrast to the preceding 6th Research Framework Programme (FP6), the current FP7 explicitly mentions (Article 6 (3)) research on human embryonic stem cells. This research area was not, however, excluded from the previous FP6, even although it was not explicitly mentioned.

The discussions in the Council of Ministers at the time were extremely difficult, with 8 Member States having reservations concerning EU funding of research with human embryos and/or human embryonic stem cells: Austria, Germany, Luxembourg, Italy, Lithuania, Malta, Poland and Slovakia. Slovenia had also at one stage supported stricter ethical limits, but then withdrew its reservations.

On 24 July 2006, the Competitiveness Council (Council of Ministers) reached a political agreement on FP7. The agreement became possible because Germany, Italy and Luxembourg accepted the following compromise: Whilst the text of Article 6 of FP7 remained unchanged, the European Commission made the following declaration[62]: "*The European Commission will continue with the current practice and will not submit to the Regulatory Committee proposals for projects which included research activities which destroy human embryos, including for the procurement of stem cells. The exclusion of funding of this step of research will not prevent Community funding of subsequent steps involving human embryonic stem cells.*"

With their support, the necessary qualified majority for the adoption of FP7 was reached. Five Member States voted against FP7 for ethical reasons (Austria, Lithuania, Malta, Slovakia and Poland).

Brief evaluation

The provisions for ethical limits are comparable with those in the preceding FP6. Intensive work during the whole legislative process by different groups aiming at an improvement of the ethical regulations in FP7 did not succeed in convincing a majority in the EP (even although a compromise amendment failed to be adopted by

[62] Full text of the Commission declaration (OJ L 412/42 of 31 December 2006): eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:412:0042:0043:EN:PDF

only a very slim margin) or achieving a sufficiently strong coalition in the Council of Ministers. At Council of Ministers level, there was a coalition of Member States against the Commission proposal (on ethics) as such, but they were not united in what they wanted to achieve, especially whether they wanted to exclude funding for any research with human embryos and/or human embryonic stem cells or whether they wanted to introduce a cut-off date for the use of human embryonic stem cells. In any case, they did not agree on a common strategy.

It must also be taken into account that the pressure to finalise the Council's position on FP7 was immense, because otherwise the start of the whole FP7 Programme would have had to be delayed; moreover, the majority of Member States were very keen to adopt the Commission proposal as it stood.

COMECE's position: COMECE[63] and its Secretariat have always argued against EU funding for research involving the destruction of human embryos and the use of human embryonic stem cells on two levels:

a) that research implying the destruction of human embryos is against human dignity: and

b) that the EU should fully respect the different national positions, thereby refraining from financing research areas which touch on the essence of human life and are forbidden by law in several Member States.

Apart from the fact that the European Parliament and the Council of Ministers deliberately decided not to exclude joint research funding from this ethically contentious research area (by excluding EU-funding for research involving human embryos and human embryonic stem cells), it is particularly regrettable that

- not even a cut-off date was included in the Commission statement that would have restricted research with human embryonic stem cells to those stem cells that were already in existence at the moment of

[63] COMECE declaration "EU Research-Funding and Ethics", www.comece.eu/site/article_list.siteswift?so=all&do=all&c=download&d=article%3A3232%3A1

the adoption of FP7; this leads to the paradoxical result that whilst researchers have to find other funds for the destruction of human embryos, research with human embryonic stem cells created by means of this other research can then be funded by the EU;

- the declaration of the European Commission was not included in the actual text of FP7 (Article 6); this gives it a legally much weaker position, and it is questionable whether this declaration will continue to be binding for the next Commission (as of 2010). This "construction" of a "Commission declaration" is a political instrument – and in a way it illustrates the multiple ways of negotiating a "political compromise".

Having said this, the very fact that research with human embryos and human embryonic stem cells was an issue of such heated debate both in the European Parliament and the Council of Ministers should not be underestimated as a sign of "success" - it has become very clear that there is substantial opposition to this research both in the European Parliament and in the Member States, even if this opposition was not strong enough to exclude joint funding by the EU for this kind of research.

Implementation of the 7th Research Framework Programme

The European Commission is responsible for the implementation of the specific Research Programmes (for example Article 7 (1) of the specific research programme "*Cooperation*"[64]).

When it comes to research projects involving the use of human embryos or human embryonic stem cells, the following additional procedures apply:

> In addition to the scientific review, the European Commission carries out an "ethics review"[65]. For this, the European Commission recruits participants for multi-disciplinary ethics committees that examine a batch of applications for research grants (research projects involving human subjects (in particular

[64] Full text of the specific research programme: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:400:0086:0242:EN:PDF

[65] Information on the Commission's ethics review see: cordis.europa.eu/fp7/ethics_en.html

children and human embryos), human embryonic stem cells, animals). As for the ethical criteria to be adopted by these (European) ethics committees, the European Commission established a number of guidelines, some of which have been elaborated by the European Group on Ethics (EGE) in its Opinion no. 22 (see above 1.3.A).

Also, the approval of a *national* ethics committee must be presented, and obviously the research project must comply with the ethical standards and laws of the Member State where the research project is carried out.

Furthermore, whenever an application for an EU research grant implies the use of human embryos or human embryonic stem cells, the final decision cannot be taken by the European Commission alone, but requires the cooperation of a ***Regulatory Committee***, that is in cooperation with the Council of Ministers (Article 7 (3), Article 8 of the first specific research programme "*Cooperation*"[66] referring to Articles 5, 7 of the *Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission*[67]).

According to this Council Decision, the European Commission is assisted by a ***Regulatory Committee*** which is composed of representatives from each Member State and which is chaired by a representative of the Commission. The Regulatory Committee decides by qualified majority; the votes of the representatives of the Member State within the Committee are weighted as in the Council of Ministers.

[66] Article 7 of the Specific Programme "Cooperation": "
First paragraph: "*The European Commission shall be responsible for the implementation of the Specific Programme*"
Third paragraph: "*The regulatory procedure laid down in Article 8(3) shall apply for the adoption of the following measures: ... b) the approval of the funding of actions involving the use of human embryos and human embryonic stem cells*."
Article 8 (3) of the Specific Programme:
"*Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply. The period laid down for in Article 5(6) of Decision 1999/468/EC shall be set at two months*."

[67] Council Decision 1999/468/EC, 28 June 1999, laying down the procedures for the exercise of implementing powers conferred on the Commission; OJ L 184/23, 17 July 1999. Full text: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1999:184:0023:0026:EN:PDF

If a certain application for a research grant does not receive the support of a qualified majority, the European Commission has to submit the proposal to the Council of Ministers and to inform the European Parliament. Within two months the Council of Ministers itself can adopt or oppose the proposed measure. However, an application can only be rejected by qualified majority in the Council of Ministers according to Article 5 (6) of the Council Decision (EC) 1999/468.

It is therefore via their representatives in the Regulatory Committee that the Member States are involved in – and informed about – pending funding decisions. What makes transparency more difficult is the fact that it is the members of the "Programme Committee" who act as a "Regulatory Committee" when it comes to making decisions on EU funding of research projects involving, for example, the use of human embryonic stem cells. The main task of the Programme Committee, however, is to address the different thematic priorities in each specific research programme. In other words, the members of the Regulatory Committee do not have any particular expertise in the ethical evaluation of research projects involving, for example, human embryonic stem cells.

In any case, the involvement of the Regulatory Committee (and, thus, representatives of Member States) will *de facto* lead only to a certain delay since, as in the Council of Ministers; a rejection of an application for funding would require a qualified majority.

Forthcoming procedure

FP 7 prescribes that "*The fields of research set out above shall be reviewed for the second phase of this programme (2010-2013) in the light of scientific advances*" (Article 4 (4) of FP7). This *mid-term revision* of the ethical limits to EU-funded research is expected to take place after the new Commission are in place by the end of 2009/2010. Evidently, the debate could open the way for good or ill (e.g. to allow for EU funding of so-called therapeutic cloning).

1.5 Legislation based on Article 177ff EC Treaty (Development Cooperation)

A. Regulation (EC) no. 1567/2003[68] on aid for policies and actions on reproductive and sexual health and rights in developing countries

The Regulation aimed at the specific field of reproductive and sexual health and rights in developing countries. It emphasises (recital no. 9) that "*the Community and its Member States are determined to make a full contribution towards achieving the Millennium Development Goals of reducing by three-quarters the rate of maternal mortality, achieving gender equality, and attaining access to sexual and reproductive health care and services worldwide*". Whilst the Regulation states (recital 16) that "*no support is to be given under this Regulation to incentives to encourage sterilisation or abortion*", and that "*abortion should in no case be promoted as a method of family planning*", this gives scope for the conclusion that abortion would be provided for in other circumstances. This is also supported by the purpose of the Regulation as laid down in its Article 1: "*The Community shall support actions to improve reproductive and sexual health in developing countries and to secure respect for the rights relating thereto*."

According to Article 3 of the Regulation, Community financial support shall be given... to "*ensure better access to high-quality reproductive and sexual health services, offering, in particular, contraceptive choice*" and to "*reduce unsafe abortions by decreasing the number of unwanted pregnancies through the provision of family planning services*".

The discussions on this Regulation were very animated in the European Parliament. Two amendments – one proposing to include the clarification that abortion was not a "reproductive service", the other to state that EU money would not be used to provide for abortions – were rejected. This must be interpreted as meaning that the majority of the European Parliament also supported EU financing

[68] Official Journal L 224/1, 6 September 2003, full text: http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=EN&numdoc=32003R1567

of abortion services in developing countries if they were legal in the respective country.

The financial framework for the implementation of this Regulation was set at 83.95 million EUR (for the period of 2003-2006). The Regulation was in force between 9 September 2003 and 31 December 2006.

B. *Regulation No. 1905/2006 establishing a financing instrument for development cooperation*

With the adoption of the financial perspectives of the EU for 2007-2013, a new framework for development co-operation was drafted for the same period. The financial reference amount for the implementation of this Regulation[69] over the period 2007-2013 is 16 897 million EUR (Article 38 (1) of the Regulation).

The Regulation, which is based on Article 179 EC Treaty, emphasises in its recitals that the following values are fundamental to long-term development: a political environment which guarantees peace and stability, respect for human rights, fundamental freedoms, democratic principles, the rule of law, good governance and gender equality. The original Commission proposal did not make any reference to "reproductive rights" nor did the European Parliament adopt amendments along these lines in its first reading. However, during the negotiations in the Council of Ministers, a reference was included.

The Regulation as finally adopted contains the following references:

- Article 5 (2b)i)): *increasing access to and provision of health services for lower income population groups and marginalised groups, including women and children, persons belonging to groups subject to ethnic, religious or any other discrimination and persons with disabilities, with a central focus on the related MDGs, namely reducing child mortality, improving maternal and child health and* ***sexual and reproductive health and rights*** *as set out in the Cairo Agenda of the International Conference on Population and Development (ICPD), addressing poverty diseases, in particular HIV/AIDS, tuberculosis and malaria;*

[69] Official Journal L 378/41, 27 December 2006; full text: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:378:0041:0071:EN:PDF

- Article 12 (2a)ii)): *in line with the principles agreed at the ICPD and ICPD + 5, support actions to improve reproductive and sexual health in developing countries and to secure the right of women, men and adolescents to good reproductive and sexual health and provide financial assistance and appropriate expertise with a view to promoting a holistic approach to, and* ***the recognition of, reproductive and sexual health and rights as defined in the ICPD Programme of Action****, including safe motherhood and universal access to a* ***comprehensive range of safe and reliable reproductive and sexual health care and services****, supplies, education and information, including information on all kinds of family planning methods.*

II. EU LEGISLATION UNDER DISCUSSION IN JULY 2009

2.1 Proposal for a Directive for the protection of animals used in scientific experiments

On 5 November 2008 the European Commission issued a proposal for a Directive[70] based on Article 95 of the EC Treaty. The draft Directive aims at establishing measures for the protection of animals used or intended to be used for scientific purposes in the EU. One of the main features of the Directive is its aim to replace and reduce the use of animals in procedures and the refinement of the breeding, accommodation, care and use of animals in procedures (Article 1).

When it comes to the principle of "replacement, reduction and refinement" of animal tests, this principle requires to be supported in so far as it helps to treat animals with a dignity appropriate to them, as part of creation. A problem arises in so far as currently research continues with the aim of developing *toxicity testing on the basis of human embryonic stem cells*. Such research is also conducted with the financial support of the European Community under the FP6 and FP7[71].

[70] COM (2008)543 dated 5 November 2008, full text: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0543:FIN:EN:PDF

[71] Project synopses: "Alternative Testing Strategies: Replacing, reducing and refining the use of animals in research"; published by DG Research of the European Commission, EUR 22846, 2008

This issue is not directly mentioned in the Directive or in the Explanatory Memorandum, although great emphasis is put on replacement testing methods in order to reduce animal testing.

Article 4 of the Commission's proposal for the Directive reads: "*Where a method of testing not involving the use of animals exists and may be used in place of a procedure, Member States shall ensure that the alternative method is used"*. That means that, if a testing method were to be available using human embryonic stem cells, then "*Member States shall ensure that the alternative method is used"*.

The European Parliament proposed an amendment to this Article so as to ensure that Member States would in no way be obliged to apply testing methods involving ethically contentious cells such as human embryonic or foetal cells as the basis for toxicology tests. The following amendment was adopted by the plenary on 5 May 2009[72]:

Article 4 paragraph 1:

1. Where a method of testing, experimentation or other scientific activity not involving the use of living animals exists which, from a scientific point of view, is a satisfactory method or testing strategy for obtaining the result sought and which may be used in place of a procedure, Member States shall ensure that the alternative method is used, ***provided that the alternative method is not prohibited in the Member State concerned. Pursuant to this Directive, testing methods which involve the use of human embryonic and foetal cells shall not be regarded as alternatives, which means member states can make their own ethical decisions.***

Forthcoming procedure

In the applicable "co-decision" procedure, the Council of Ministers has to come to an agreement as to whether it accepts the European Parliament's proposal. Currently, the Research working group of the Council is discussing the Commission proposal and the Parliament report. There is not yet a date fixed for a meeting of the Council of Ministers to decide on this proposal.

[72] Text of the report adopted by the European Parliament on 5 May 2009: www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2009-0343&language=EN&ring=A6-2009-0240

Brief evaluation

The proposal of the European Parliament is the minimum necessary in order to safeguard the liberty of Member States to prohibit or restrict the use of human embryonic stem cells or foetal cells in their country. The original proposal of the European Commission would possibly impose on Member States the use of ethically contentious practices involving the human embryo and derived cells. It is to be hoped that the Council of Ministers will ensure that no Member State will be obliged by the proposed Directive to apply testing strategies involving the use of human embryonic stem cells and other embryonic or foetal cells.

2.2 Proposal for a Directive on organ donation and transplantation

Another legislative proposal for a Directive, presented by the European Commission on 8 December 2008, is based on Article 152 (4a) EC Treaty: ***Directive on standards of quality and safety of human organs intended for transplantation***[73]. The proposed Directive aims at ensuring quality and safety for patients at EU level, ensuring the protection of donors, and facilitating cooperation between Member States and cross-border exchanges.

This EU initiative to promote organ donation and transplantation and to help improve efficacy is to be welcomed as long as it is guided by absolute respect for the dignity of the donor and of the recipient. The following ethical issues are particularly important:

- the *principle of non-commercialisation*: Article 13 (1): *Member States shall ensure that donations of human organs from deceased and living donors are voluntary and unpaid.*

- *free and informed consent*: Regarding the requirements for consent, the Directive refers to the rules of the Member States (Article 14): *Procurement shall be carried out only after compliance with all mandatory consent or authorisation requirements in force in the*

[73] COM (2008)818, 8 December 2008; full text: http://ec.europa.eu/health/ph_threats/human_substance/oc_organs/docs/organs_directive_en.pdf

Member State concerned. That means that the Member State is free to make a decision on opting-in or opting-out.

Forthcoming procedure:

The co-decision procedure applies; the Directive will therefore have to be adopted jointly by the European Parliament and the Council of Ministers

In the European Parliament, the lead Committee is the Committee for Environment, Public Health and Food Safety (ENVI); Ms Frieda Brepoels (EPP) was nominated as *rapporteur*. An opinion will be provided by the Legal Affairs Committee of the European Parliament, the *rapporteur* being Mr Jaroslav Zverina (EPP)

Ms Brepoels presented a working document[74] on 12 March 2009. It is expected that she will present a draft report at the beginning of the new legislature in autumn 2009 (provided that the European Parliament decides to continue the pending legislative procedures).

2.3 Proposal for a Directive on the application of patients' rights in cross-border healthcare

On 2 July 2008, the European Commission proposed a ***Directive on the application of patients' rights in cross-border healthcare***[75], based on Article 95 of the EC Treaty (internal market).

This Directive aims at the establishment of a Community framework for cross-border healthcare. The European Court of Justice had recognised in several decisions[76], that

- health services which are provided for remuneration must be regarded as services within the meaning of the Treaty, and

[74] www.europarl.europa.eu/meetdocs/2004_2009/documents/dt/774/774624/774624en.pdf

[75] COM (2008) 414, 2 July 2008; full text: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0414:FIN:EN:PDF

[76] Case C-158/96 Kohll [1998] ECR I-1931; Case C-120/95 Decker [1998] ECR I-1831; Case C-368/98 Vanbraekel [2001] ECR I-5363; Case C-157/99 Smits and Peerbooms [2001] ECR I-5473; Case C-56/01 Inizan [2003] ECR I-12403; Case C-8/02 Leichtle [2004] ECR I-2641; Case C-385/99 Müller-Fauré and Van Riet [2003] ECR I-4503; Case C-372/04 *Watts* [2006] ECR I-4325.

- in the context of the free movement of services, patients also had the right to reimbursement of healthcare services under certain conditions.[77]

The Commission proposal suggests that:

- any non-hospital care to which citizens are entitled in their own Member State, they may also seek in another Member State without prior authorisation, and be reimbursed up to the level of reimbursement provided by their own system; and

- any hospital care to which they are entitled in their own Member State they may also seek in any other Member State; however, the Directive allows Member States to provide for a system of prior authorisation for reimbursement of costs for hospital care provided in another Member States under certain conditions.

Bioethical issues

- From the perspective of the health systems of Member States as well as from the perspective of the principle of subsidiarity in regard to the ethical decisions taken by Member States, it is important that the proposal for a Directive ensures the right of the Member States to impose the same conditions that apply domestically and the right to define the benefits that they choose to provide. In other words: If a Member State does not include a particular treatment as part of the entitlement of their citizens at home, the proposed Directive will not create any new entitlement for patients to have such a treatment abroad and be reimbursed.

  For the adoption of the Directive, the co-decision procedure applies; therefore the Directive has to be adopted jointly by the European Parliament and the Council of Ministers.

  The European Parliament adopted a legislative resolution amending the proposal for a Directive on 23 April 2009 in its first reading (*rapporteur*: Mr Bowis (EPP)). The Parliament re-

[77] For more information, see the Communication of the European Commission COM(2006)1195 dated 26 September 2006, section 2.1; full text: ec.europa.eu/health/ph_overview/co_operation/mobility/docs/comm_health_services_comm2006_en.pdf

emphasises that the national competence in the organisation and delivery of healthcare must be fully respected. However, when it comes to rare diseases, the Parliament proposes that patients should have the right to access healthcare in another Member State and to get reimbursed even if the treatment in question is not among the benefits provided for in the legislation of the Member State of origin.

- Another issue concerns the recognition of prescriptions issued in another Member State: the recognition of such a prescription shall not affect any professional or ethical duty that would require the pharmacist to refuse to dispense had the prescription been issued in the Member State of affiliation. Where a prescription is issued in the Member State of treatment which is not normally available on prescription in the Member State of affiliation, it shall be for the latter to decide whether to authorise exceptionally or to provide an alternative medicinal product deemed to be as effective.

The Council of Ministers is currently negotiating the draft Directive in its first reading; it is expected that the Council of Ministers will reach a political agreement by the time of the December 2009 meeting of the EPSCO.

III. OTHER MEASURES

3.1 European Commission

Besides the legislative proposals and the research framework programmes, the European Commission promotes discussions on different issues which also raise bioethical aspects. The following section provides some examples:

A. Genetic Testing

The European Group on Ethics, an advisory body to the European Commission, issued Opinion no. 18[78] on the "*Ethical Aspects of Genetic Testing in the Workplace*" (28 July 2003).

The Institute for Prospective Technological Studies in Seville, part of the EU Joint Research Centre, issued in 2003 a report "*Towards quality assurance and harmonisation of genetic testing services in the EU*"[79]. The report reviews the dimensions of genetic testing in the EU, in terms of active laboratories, conditions tested and numbers of tests and evaluates the state of quality assurance in these services.

In 2004, an expert group set up by the Directorate General for Research of the European Commission presented ***25 recommendations on the legal, ethical and social implications of genetic testing***[80]. The European Commission organised a conference "*Human Genetic Testing – What Implications*" on 6/7 May 2004 where these 25 recommendations were presented and discussed.

In 2005, DG Research of the European Commission issued a "*Survey on national legislation and activities in the field of genetic testing in EU Member States*"[81]. This Survey refers to the 2nd progress report dated 6 April 2004 on "*Life Sciences and Biotechnology – a Strategy for Europe*" (see 3.1.E, p.70), which highlighted that "*the various activities undertaken regarding genetic testing at European and international level have indicated the need for a co-ordinated*

[78] Full text: ec.europa.eu/european_group_ethics/publications/docs/avis18_compl_en.pdf
[79] Report EUR 20977 EN; full text: ftp.jrc.es/EURdoc/eur20977en.pdf
[80] Full text: ec.europa.eu/research/conferences/2004/genetic/pdf/recommendations_en.pdf
[81] Full text: ec.europa.eu/research/biosociety/pdf/bioethics-survey-test2106.pdf

approach on this emerging field within the Commission services and with the Member States".

The survey furthermore refers to the priorities for future activities to be undertaken by the European Commission and Member States in the field of genetic testing identified by the 2nd progress report:

- to engage in *EU-wide co-ordination of efforts* to ensure the highest quality of genetic testing in the EU and beyond;

- to establish *EU- wide networking of national centres* for exchange of information regarding quality assurance of genetic testing including training activities**,**

- and *EU- wide networking for genetic testing of rare diseases*.

The survey states that "*without any intention to interfere with Member States' competence regarding genetic testing, DG Research has established an informal working group involving officials and experts from Member States to ensure exchange of information and to identify actions which should be addressed at EU level in order to assure the highest quality of genetic testing*."

B. Nanotechnologies

Nanosciences and nanotechnologies are considered to be an important part of European research policy, and a vital element for the competitiveness of EU research.

In 12 May 2004, the European Commission issued a Communication: ***Towards a European Strategy for Nanotechnology***[82]. It provides a series of recommendations and initiatives on how to strengthen European Research and Development in the field. The Communication also highlights the need to identify and address safety, health and environmental concerns associated with nanotechnologies. It aims at addressing any environmental, health, safety and societal concerns upfront. The

[82] COM(2004)338, full text: ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/nano_com_en.pdf

European Commission furthermore carried out a Consultation in which the COMECE Secretariat participated.

On 7 June 2005, a Commission Communication: "*Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009*"[83] was published.

Subsequently, the European Commission issued, on the basis of Article 211 of the EC Treaty,[84] a ***Recommendation on a Code of conduct for responsible nanosciences and nanotechnologies research***[85]. This code of conduct does not have legal standing, it is primarily a basis for discussion. The Commission organised a public conference to discuss the Code of Conduct on 7/8 May 2008[86]. It is noteworthy, that the Commission proposes a commitment to refrain from using nanotechnologies for human enhancement purposes (point 4.1.16 of the Code of Conduct[87]).

C. Organ donation and transplantation

Organ donation and transplantation: Policy actions at EU level

Preceding the Proposal for a Directive on organ donation and transplantation, issued on 8 December 2008 (see above 4.2.2), the European Commission adopted, on 30 May 2007, a Communication "*Organ donation and transplantation: Policy actions at EU level*"[88].

Organ donation: Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States

[83] COM(2005)243, full text: ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/nano_action_plan2005_en.pdf. More information on the action plan and the European Commission's activities is available at: cordis.europa.eu/nanotechnology/actionplan.htm

[84] Article 211 EC Treaty: *In order to ensure the proper functioning and development of the common market, the Commission shall: ... - formulate recommendations or deliver opinions on matters dealt with in this Treaty, if it expressly so provides or if the Commission considers it necessary; ...*"

[85] C(2008)424, 7 February 2008, full text: ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf

[86] ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1640

[87] Point 4.1.16 of the Code of Conduct: *N&N research organisations should not undertake research aiming for non-therapeutic enhancement of human beings leading to addiction or solely for the illicit enhancement of the performance of the human body.*

[88] COM(2007)275, 30 May 2007; full text: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0275:FIN:EN:PDF

In tandem with the presentation of the Directive on organ donation and transplantation on 8 December 2008, and due to the limited legislative competence of the EU in the field of health policy (restricted to the coordination of health policies), the European Commission proposed an "*Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States*"[89]. It aims at strengthening cooperation between Member States, through the identification and development of common objectives and guidelines, jointly agreed indicators and benchmarks, regular reporting and identification and sharing of best practices.

The Commission identifies 3 main challenges and proposes several objectives with concrete proposals for action:

Challenge 1: Increasing organ availability

- Objective 1: Member States should aim to achieve full potential in every hospital where there is potential for organ donation
- Objective 2: Member States should promote living donation programmes following best practices
- Objective 3: Increase public awareness of organ donation

Challenge 2: Enhancing the efficiency and accessibility of transplant systems

- Objective 4: Support and guide transplant systems to become more efficient and accessible

Challenge 3: Improving quality and safety

- Objective 5: Improve the quality and safety of organ donation and transplantation

D. Life Sciences and Biotechnology

In 2002, the Commission adopted the Communication "*Life Sciences and Biotechnology – A Strategy for Europe*"[90]. This Communication

[89] COM (2008) 819 final; full text: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0818:FIN:EN:PDF

[90] COM(2002)27 final, 23 January 2002, full text:

sets out a roadmap up to 2010 and put the sector at the forefront of those technologies which should contribute to the goal of the Lisbon Strategy (EU competitiveness). It consists of two parts:

- policy orientations and
- a 30 point action plan.

There have been several progress reports and a mid-term review in 2007[91].

E. Science and Society

At the request of the Council of Ministers (Research Council) of 26 June 2001, the Commission presented a Communication "*Science and Society Action Plan*"[92] in 2002. The aim is to support the Lisbon goals and the creation of a European Research Area.

The Action Plan has three main aims:

- to promote scientific and education culture in Europe,
- to bring science closer to the citizens and
- to put responsible science at the heart of policy making.

3.2 European Parliament

The European Parliament as co-legislator plays an important role in bioethical issues in the field of legislative proposals. Apart from its part in the legislative process, the European Parliament has different tools for stimulating political debate without, however, any direct legislative impact. In the field of bioethics, the European Parliament has used some of these approaches: for example, by means of public workshops or conferences or Parliamentary Resolutions. Parliamentary Resolutions can be adopted as a response to a Communication published by the European Commission (see for example the report on genetic testing below), or else as an "own-

[91] ec.europa.eu/biotechnology/pdf/policypaper_en.pdf
ec.europa.eu/biotechnology/reports_en.htm

[92] COM(2001) 428, 25 July 2001; europa.eu.int/comm/research/science-society/action-plan/action-plan_en.html

initiative report". Other measures are written declarations[93] and Parliamentary Questions[94] by MEPs to the European Commission.

The following section provides some examples:

A. *Genetic testing*

The European Parliament had by 1989 already adopted a ***Resolution on the ethical and legal problems of genetic engineering***[95]. In this Resolution, the Parliament emphasised freedom of research whilst also referring to the "*restraints imposed on the freedom of science and research"*, arising in particular from the "*dignity of the individual and of the sum of all individuals*" (paragraph 8 and 9). The Parliament "*believes that the legislator has an absolute duty to define these limits*" (paragraph 10). In this Resolution, it proposes the creation of an "*international, pluralistic commission for the ethical, social and political evaluation of the results of human genome research and their possible applications*". "*This Commission should be made up of Members of the European Parliament, members of the national parliaments of the Member States, delegates from organizations representing the interests of those particularly affected (women, workers, consumers, the disabled etc) and experts*"

[93] A **written declaration** is a text of a maximum of 200 words on a matter falling within the European Union's sphere of activities. MEPs can use written declarations to launch or relaunch a debate on a subject that comes within the EU's remit. A group of up to five MEPs can submit a written declaration by presenting a text to be signed by their colleagues. If the declaration is signed by a majority of the MEPs, it is forwarded to the President, who announces it in plenary. At the end of the part-session, the declaration is forwarded to the institutions named in the text, together with the names of the signatories. (see Rule 116: Written declaration)

[94] **Rule 110: Questions for written answer to the Council or the Commission**
1. Any Member may put questions for written answer to the Council or the Commission in accordance with guidelines laid down in an annex to these Rules of Procedure. The content of questions shall be the sole responsibility of their authors.
2. Questions shall be submitted in writing to the President who shall forward them to the institution concerned. Doubts concerning the admissibility of a question shall be settled by the President. His decision shall be notified to the questioner.
3. If a question cannot be answered within the time limit set it shall, at the request of the author, be placed on the agenda of the next meeting of the committee responsible. Rule 109 shall apply mutatis mutandis.
4. Questions which require an immediate answer but not detailed research (priority questions) shall be answered within three weeks of being forwarded to the institution concerned. Each Member may table one priority question each month.
Other questions (non-priority questions) shall be answered within six weeks of being forwarded to the institution concerned.
Members shall indicate which type of question they are submitting. The final decision shall be taken by the President.
5. Questions and answers shall be published in the Official Journal of the European Union.

[95] Official Journal C 96, 17/04/1989 p.165-171, full text: www.codex.vr.se/texts/EP-genetic.html#2

(paragraph 5). This proposal, however, was not put into practice. As regards research on human embryos, the Parliament considers in paragraph 32 that "*procedures involving live human embryos or foetuses … are justified only if they are of direct or otherwise unattainable benefit in terms of the welfare of the child concerned and its mother…*".

On 21 November 2002, the European Parliament adopted a Resolution[96] on the *Commission Communication on Life sciences and biotechnology – a Strategy for Europe* (see above point 4.3.1.5). In this Resolution, the European Parliament

- *"solemnly reaffirms that the life and dignity of all human beings, whatever their stage of development and state of health, must be respected and is opposed to any form of research or use of life sciences and biotechnology that runs counter to this fundamental principle"* (paragraph 53);

- *"calls on the Commission to take the necessary steps for an EU-wide regulation on DNA-testing, choosing, if possible, a legal basis (e.g. Article 152 (health) or Article 153 (consumer protection)) which leaves Member States free to introduce more stringent protection measures and asks its competent Committee, subject to prior authorisation by the Conference of Presidents, to consider drafting an own-initiative report on the legal aspects of DNA testing"* (paragraph 55);

- *"considers it particularly important to ensure that no woman is compelled to have prenatal diagnosis carried out and that any decision not to resort to such diagnosis is respected and supported"* (paragraph 56).

B. *Human cloning*

The European Parliament had already adopted a first ***Resolution on the cloning of the human embryo*** on 28 October 1993[97].

"*Alarmed by reports in the international press that the first known cloning of human embryos has taken place" (Recital A),* the

[96] Official Journal C 25 E/384, 29 January 2004, full text: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2004:025E:0384:0390:EN:PDF

[97] Official Journal C 315, 22 November 1993, page 224, full text: www.europarl.europa.eu/comparl/tempcom/genetics/links/b3_1519_en.pdf

European Parliament is *"concerned that similar experiments and practices could be taking place in the European Community, both in the context of publicly funded research and in the private sector" (Recital D)*. Therefore, the European Parliament *"condemns the cloning of humans for any purpose whatsoever, including research, as a grave violation of fundamental human rights, contrary to respect for the individual, morally repugnant, and ethically unacceptable"* (paragraph 1). It called on the European Commission *"to submit immediately a proposal for a Council Decision prohibiting throughout the European Community the cloning of human beings for any purpose whatsoever, including research"* (paragraph 2)

In its ***Resolution on cloning*** adopted on 14 April 1997[98], the European Parliament stated its condemnation of human cloning in no uncertain terms (recital B):

"*In the clear conviction that the cloning of human beings, whether experimentally, in the context of fertility treatment, preimplantation diagnosis, tissue transplantation or for any other purpose whatsoever, cannot under any circumstances be justified or tolerated by any society, because it is a serious violation of fundamental human rights and is contrary to the principle of equality of human beings as it permits a eugenic and racist selection of the human race, it offends against human dignity and it requires experimentation on humans*.

Furthermore, it

1. *Stresses that each individual has a right to his or her own genetic identity and that human cloning is, and must continue to be, prohibited;*
2. *Calls for an explicit worldwide ban on the cloning of human beings;*
3. *Urges the Member States to ban the cloning of human beings at all stages of formation and development, regardless of the method used, and to provide for penal sanctions to deal with any violation;*

[98] Official Journal C 115, 14 April 1997, page 92, full text: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:51997IP0209:EN:HTML

On 15 January 1998, the European Parliament adopted a ***Resolution on human cloning***[99] in which it "*reiterates that every individual has the right to his own genetic identity and that human cloning must be prohibited*" (paragraph 1). It "*calls on each Member State to enact binding legislation prohibiting all research on human cloning within its territory and providing for criminal sanctions for any breach*" (paragraph 3). Moreover, it "*calls on the Member States, the European Union and the United Nations to take all the steps necessary to bring about a universal and specific ban, which is legally binding, on the cloning of human beings, including the convening of a world conference on this subject*" (paragraph 4).

On 30 March 2000, the European Parliament adopted another ***Resolution on human cloning***[100].

It "*considers that 'therapeutic cloning', which involves the creation of human embryos solely for research purposes, poses a profound ethical dilemma, irreversibly crosses a boundary in research norms and is contrary to public policy as adopted by the European Union*" (paragraph 2). It "*repeats its call to each Member State to enact binding legislation prohibiting all research into any kind of human cloning within its territory and providing for criminal penalties for any breach"* (paragraph 4).

In the European Parliament's ***Resolution on the relations between the European Union and the United Nations*** adopted on 29 January 2004, the European Parliament "*reiterates its call for a worldwide ban on the cloning of humans, and supports Costa Rica's initiative in this connection and the UN General Assembly's decision to work on a corresponding convention in 2004*" (paragraph 26). The Costa Rican proposal related to a comprehensive ban, not only of reproductive cloning, but also of so-called therapeutic cloning.

[99] Official Journal C 034, 2 February 1998, page 164, full text: http://eur-lex.europa.eu/Notice.do?val=325432:cs&lang=en&list=249519:cs,325432:cs,319039:cs,197110:cs,&pos=2&page=1&nbl=4&pgs=10&hwords=Resolution~cloning~&checktexte=checkbox&visu=#texte

[100] Official Journal C 135, 7 May 2001.

C. *Trade in human egg cells*

On 10 March 2005, the EP adopted an own-initiative ***Resolution on the trade in human egg cell trade***[101]. Following media reports which uncovered the existence of a clinic in Romania specialising in the donation of egg cells in return for financial compensation and subsequent to a consultation paper of the UK Human Fertilisation and Embryology Authority (HFEA) in which a payment of 1000 Pounds to a donor is an option, the European Parliament restated that the human body should not be a source of financial gain and considers that the activities of the clinic in Romania and similar bodies are unacceptable, because they can be regarded as trade.

In this Resolution, the European Parliament also adopted a paragraph relating to EU research funding:

"*Asks the Commission to apply the subsidiarity principle in connection with other forms of embryo research and embryonic stem cell research so that Member States in which this kind of research is legal fund it from their national budgets; considers that EU funding should concentrate on alternatives like somatic stem cell and umbilical cord stem cell research, which are accepted in all Member States and have already led to successful treatment of patients*." (paragraph 15).

D. *Patents for biotechnological inventions)*

In its ***Resolution on patents for biotechnological inventions***[102], adopted on 26 October 2005, the European Parliament takes a clear position against the patentability of human embryonic stem cells. At the same time, a majority of the Parliament supports an amendment condemning research on human embryos which destroys the embryo:

3. Supports further stem-cell research and other alternatives to promote human health but underlines its fundamental position regarding the application of biotechnology to human beings, especially the rejection of interventions in the human germ line, the rejection of cloning of the human being in all phases of its development and the rejection of research on human embryos, which destroys the embryo;

[101] Full text: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2005:320E:0251:0253:EN:PDF

[102] Full text: www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2005-0407&language=EN

14. Insists that the creation of human embryonic stem cells implies the destruction of human embryos and that therefore the patenting of procedures involving human embryonic stem cells or cells that are grown from human embryonic stem cells is a violation of Article 6(2)(c) of the Directive

E. *Organ donation and transplantation*

In reaction to the Commission Communication "*Organ donation and transplantation: Policy actions at EU level*", the European Parliament adopted a ***Resolution on organ donation and transplantation: Policy Actions at EU level***[103] on 22 April 2008.

The COMECE Secretariat, together with the Katholisches Büro, (the political liaison office of the German Catholic Bishops' Conference) and the office of EKD (the German Protestant Church), were in contact with the *rapporteur* in the European Parliament. Whilst general support for organ donation was expressed, it was highlighted *inter alia* that organ donation may not be treated as a marketable product, but that it must always be a free gift offered out of compassion to fellow human beings. Some of the concerns were taken on board in the European Parliament Resolution, in particular:

paragraph 7: *Points out that organ donation is a gift; therefore stresses that, while finding an answer to the severe shortage of organs in the EU is extremely important, the freedom of choice as to whether or not to donate an organ needs to be respected and protected as well*;

paragraph 21: *Underlines the need to ensure that organ donations stay strictly non-commercial*.

F. *Cloning of animals for food supply*

In its ***Resolution on the cloning of animals for food supply***[104], adopted on 3 September 2008, the European Parliament called for a

[103] European Parliament Resolution on organ donation and transplantation: Policy actions at EU level (2007/2210 (INI)), full text: www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2008-0130&language=EN&ring=A6-2008-0090

[104] Full text: www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2008-0400+0+DOC+XML+V0//EN&language=EN

ban in the EU on the cloning of animals for food supply. The Parliament called on the Commission to "*submit proposals prohibiting for food supply purposes: the cloning of animals, the farming of cloned animals or their offspring, the placing on the market of meat or dairy products derived from cloned animals or their offspring, and the importing of cloned animals, their offspring, semen and embryos from cloned animals or their offspring, and meat and dairy products derived from cloned animals or their offspring*." The Resolution was prompted by an opinion of the US Food and Drug Administration in January 2008 that meat and milk from cloned animals "*are as safe to eat as food from conventionally bred animals*".

G. *"Sexual and reproductive rights"*[105]

In the European Parliament, a ***Resolution on Sexual and reproductive health and rights***[106] was adopted on 3 July 2002. This report, although it "*notes that the legal or regulatory policy concerning reproductive health falls within the Member States' sphere of competence and that subsidiarity applies to these areas; notes however that the EU can play a supportive role through the exchange of best practices*" (paragraph 1). It "*underlines that abortion should not be promoted as a family planning method*" (paragraph 8), yet "*recommends that, in order to safeguard women's reproductive health and rights, abortion should be made legal, safe and accessible to all*" (paragraph 12).

[105] "Sexual and reproductive health and rights" is a term that is widely used since the International Conference on Population and Development (ICPD) held in Cairo in 1994 (www.un.org/popin/icpd/conference/offeng/poa.html).
At this conference, the delegations of UN Member States agreed on the ICPD Programme of Action, although a significant number of delegations opposed the use of new terminology which is understood by many as including abortion:
According to the ECPD Programme of Action, reproductive health implies the "*right of men and women to be informed and to have access to safe, effective, affordable and acceptable methods of family planning of their choice, as well as other methods of their choice for regulation of fertility which are not against the law*" (paragraph 7.2 of the Programme of Action). According to paragraph 7.3, reproductive rights "*rest on the recognition of the basic right of all couples and individuals to decide freely and responsibly the number, spacing and timing of their children and to have the information and means to do so, and the right to attain the highest standard of sexual and reproductive health. It also includes their right to make decisions concerning reproduction free of discrimination, coercion and violence*".

[106] Full text:
www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P5-TA-2002-0359+0+DOC+XML+V0//EN&language=EN

On 4 September 2008, the European Parliament adopted a ***Resolution on Maternal Mortality ahead of the UN High-level Event on the Millennium Development Goals to be held on 25 September.*** Again, the European Parliament promoted "*access for all women to comprehensive sexual and reproductive health information and services*" (paragraph 7). Also, it "*deplores the ban on the use of contraceptives advocated by churches, as condom use is crucial in preventing diseases and unwanted pregnancies*" (paragraph 21).

The European Parliament's ***Resolution on the situation of fundamental rights in the European Union 2004-2008***[107], adopted on 14 January 2009, "*stresses the need to raise public awareness of the right to reproductive and sexual health, and calls on the Member States to ensure that women can fully enjoy these rights, to put in place appropriate sex education, information and confidential advisory services, and to facilitate access to contraception in order to prevent all unwanted pregnancies and illegal and high-risk abortions, and to combat the practice of female genital mutilation*;" (paragraph 60). Also, it "*stresses that ethnic minority women should be ensured access to public funds, irrespective of their legal status, to enable them to access safe, equal, culturally sensitive health services and rights, in particular sexual and reproductive health and rights*; (paragraph 61).

An aside concerning the debate in the Parliamentary Assembly of the Council of Europe

It is clear that the political debates of the Parliamentary Assembly of the Council of Europe and of the European Parliament are not disconnected. When it comes to the issue of "sexual and reproductive rights" and to abortion in particular, it is noteworthy that in March 2008, the Council of Europe's Parliamentary Assembly adopted *Resolution 1607 (2008)* entitled*: "Access to safe and legal abortion in Europe"*[108]. In this Resolution, the Parliamentary Assembly of the Council of Europe claims the existence of a "right of access to safe and legal abortion".

More specifically, the Parliamentary Assembly "*invites the member states of the Council of Europe to*

[107] www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2009-0019&language=EN&ring=A6-2008-0479

[108] assembly.coe.int/Main.asp?link=/uments/AdoptedText/ta08/ERES1607.htm

7.1. decriminalise abortion within reasonable gestational limits, if they have not already done so;

7.2. guarantee women's effective exercise of their right of access to a safe and legal abortion;

7.3. allow women freedom of choice and offer the conditions for a free and enlightened choice without specifically promoting abortion;

7.4. lift restrictions which hinder, de jure or de facto, access to safe abortion, and, in particular, take the necessary steps to create the appropriate conditions for health, medical and psychological care and offer suitable financial cover;

7.5. adopt evidence-based appropriate sexual and reproductive health and rights strategies and policies, ensuring continued improvements and expansion of non-judgmental sex and relationships information and education, as well as contraceptive services, through increased investments from the national budgets into improving health systems, reproductive health supplies and information;"

3.3 Council of Ministers

A. Research policy

On 29/30 May 2008, the Council of Ministers (in its "Competitiveness" configuration), adopted "*Conclusions on the Launch of the "**Ljubljana Process**" - towards full realisation of ERA (European Research Area"*[109]. This process is seen as complementary to the Lisbon Strategy. The Ljubljana Process puts special emphasis on the role of the European Research Area (ERA).

At their meeting on 2 December 2008, the Competitiveness Council adopted a "*2020 Vision for the ERA*"[110]: "*By 2020, all players will fully benefit from the "**fifth freedom**" across the ERA: **free circulation of researchers, knowledge and technology**. The ERA provides attractive conditions and effective and efficient governance for carrying out research and investing in R&D intensive sectors in Europe. It creates significant added value by fostering healthy Europe-wide scientific competition whilst ensuring the appropriate level of cooperation and coordination. It is*

[109] www.eu2008.si/en/News_and_Documents/Council_Conclusions/May/0529_COMPET-Lj_proces.pdfx
[110] ec.europa.eu/research/era/pdf/2020-vision-for-era_en.pdf

responsive to the needs and ambitions of citizens and contributes effectively to the sustainable development and competitiveness of Europe."

This aspect of the European Research Area (the "fifth freedom") may also be a source of conflict when it comes to the principle of subsidiarity and the right of a Member States to freely decide on certain fundamental bioethical choices. More concretely, if the European Research Area provides a space for the free movement of researchers, this may render it difficult in practice to uphold or to enforce certain national bioethical laws, for example those prohibiting or restricting the use of human embryonic stem cells.

B. Rare Diseases

On 8 June 2009, the Council of Ministers, after consultation with the European Parliament, adopted a ***Council Recommendation on an action in the field of rare diseases***[111].

On the basis of Article 152 (4) EC Treaty, the European Commission had proposed a ***Council Recommendation in the field or rare diseases*** in order to promote awareness of the needs of people with rare diseases and to improve the coordination and coherence of national, regional and local initiatives and to promote trans-national cooperation in fighting rare diseases. This initiative is in general to be supported.

However, in the course of the Parliamentary debate, a very problematic amendment was proposed and adopted by the plenary of the European Parliament which refers to "*pre-implantation selection of healthy embryos"*. Whilst the text insists that this should be done only when it is "*not contrary to national law and always on a voluntary basis"*, this wording is unacceptable as the "selection of healthy embryos" necessitates the destruction of "not healthy enough" embryos. However, under the applicable consultation procedure, the opinion of the European Parliament is not obligatory for the Council of Ministers; the decision on whether or not to incorporate the said amendment remains with the Council of Ministers alone.

[111] OJ C 151, 7ff, 3 July 2009; full text: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:151:0007:0010:EN:PDF

At its Council meeting (in its "Employment, Social Policy, Health and Consumer Affairs" configuration) on 8 June 2009, the Council adopted the ***Council Recommendation on action in the field of rare diseases***[112]. The above-mentioned proposal of the European Parliament was not included in the text.

The Council recommends that Member States *inter alia*

- establish and implement strategies for rare diseases in order to ensure that patients with rare diseases have access to high quality care,
- identify needs and priorities for research in the field of rare diseases and
- gather expertise on rare diseases at European level.

The Council also proposes "*the development of European guidelines on diagnostic tests or population screening, while respecting national decisions and competences*" (point V (17d) of the Recommendation).

Finally, the Council invites the European Commission to produce by the end of 2013 an implementation report on this Recommendation.

[112] www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/en/lsa/108383.pdf

CONCLUSIONS

This *tour d'horizon* of the bioethical debate at EU-level over the past 20 years makes it evident that the EU plays a more and more important role in influencing bioethical debates, at European and national levels. This takes place partly by means of legislative measures which have a more or less direct influence on the national debates, and partly by stimulation of (political) debate. Naturally, there is a danger that these ethical debates are led by a relatively small number of European specialists, failing to include the diversity of national societies within their different ethical and bioethical approaches. This debate is indeed complicated to conduct not only because of the diversity of ethical and national approaches, but equally because of the extremely rapid scientific developments which make it difficult for the societal debate to keep up to date with new discoveries.

FORESIGHT

Bearing in mind the discussion of the past years in the European institutions, there are a number of bioethical issues which keep reoccurring and others which have arisen recently. Therefore, the following issues require and deserve the attention of COMECE in the coming years:

1. the question of human anthropology in pluralistic societies
2. definition of research priorities
3. equity in access to healthcare
4. the status of human embryos and research on human embryos
5. research on human embryonic stem cells and the alternatives
6. the question of patents on human embryonic stem cells and on human genes
7. ethical questions raised by nanotechnology
8. ethical questions raised by human enhancement technologies

9. ethical questions raised by genetic testing
10. ethical questions raised by organ donation and transplantation
11. sexual and reproductive health and "rights" (in particular the question of abortion)
12. the question of conscience objection by researchers and health care workers
13. the principle of non-commercialisation of the human body and its application in human organs, tissues and cells.

MONITORING

In order to follow constructively and critically the European integration process, it is essential to be aware of the ongoing legislative and other procedures in the EU institutions. Monitoring, that is being aware of the EU discussions and procedures which have implications for bioethical issues, is the basis for dialogue with the EU institutions.

After summer 2009, the following legislative procedures will supposedly be finalised:

14. Directive for the protection of animals used in scientific procedures
15. Directive on organ donation and transplantation
16. Directive on the application of patients' rights in cross-border healthcare.

An ongoing object for monitoring is the EU's Research Framework Programme and its manner of implementation. Moreover, the revision of the ethical limits for EU funded research (7th Research Framework Programme) will take place at the end of 2009-2010. In general, the EU's research policy should be monitored, as well as the debate about the Biopatenting Directive.

DIALOGUE

On the basis of the new developments in science and the new technologies, and the growing influence of EU policies on the shaping of an ethical framework for science and medicine, it is evident that a dialogue between Church, Science, Politics and Industry is more urgently needed than ever. The promotion of such a dialogue with the relevant players at EU-level should therefore be one of the priorities for COMECE and its Secretariat in the coming years.

ANNEX :

SELECTION OF LEGAL PROVISIONS OF THE CONSOLIDATED VERSION OF THE TREATY ESTABLISHING THE EUROPEAN COMMUNITY (EC TREATY)

Excerpts (emphasis added)

CHAPTER 3
APPROXIMATION OF LAWS

Article 94

The Council shall, acting unanimously on a proposal from the Commission and after consulting the European Parliament and the Economic and Social Committee, issue directives for the approximation of such laws, regulations or administrative provisions of the Member States as directly affect the establishment or functioning of the common market.

Article 95

1. By way of derogation from Article 94 and save where otherwise provided in this Treaty, the following provisions shall apply for the achievement of the objectives set out in Article 14[113]. **The Council shall, acting in accordance with the procedure referred to in Article 251** and after consulting the Economic and Social Committee, **adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market**.

2. Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons.

3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

4. **If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30**[114], or

[113] **Article 14 EC Treaty**
1. The Community shall adopt measures with the aim of progressively establishing the internal market *over a period expiring on 31 December 1992, in accordance with the provisions of this Article and of Articles 15, 26, 47(2), 49, 80, 93 and 95 and without prejudice to the other provisions of this Treaty.*
2. The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured *in accordance with the provisions of this Treaty.*
3. The Council, acting by a qualified majority on a proposal from the Commission, shall determine the guidelines and conditions necessary to ensure balanced progress in all the sectors concerned.

[114] **"Prohibition of quantitative restrictions between Member States" (EC-Treaty):**
Article 28
Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.
Article 29
Quantitative restrictions on exports, and all measures having equivalent effect, shall be prohibited between Member States.
Article 30
The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions *on imports, exports or goods in transit* ***justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial***

relating to the protection of the environment or the working environment, **it shall notify the Commission of these provisions as well as the grounds for maintaining them.**

5. **Moreover, without prejudice to paragraph 4, if, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.**

6. **The Commission shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved** after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market. In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved. When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.

7. When, pursuant to paragraph 6, a Member State is authorised to maintain or introduce national provisions derogating from a harmonisation measure, the Commission shall immediately examine whether to propose an adaptation to that measure.

8. When a Member State raises a specific problem on public health in a field which has been the subject of prior harmonisation measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council.

9. By way of derogation from the procedure laid down in Articles 226 and 227, the Commission and any Member State may bring the matter directly before the Court of Justice if it considers that another Member State is making improper use of the powers provided for in this Article.

10. The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 30, provisional measures subject to a Community control procedure.

Article 96

Where the Commission finds that a difference between the provisions laid down by law, regulation or administrative action in Member States is distorting the conditions of competition in the common market and that the resultant distortion needs to be eliminated, it shall consult the Member States concerned. If such consultation does not result in an agreement eliminating the distortion in question, the Council shall, on a proposal from the Commission, acting by a

property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

qualified majority, issue the necessary directives. The Commission and the Council may take any other appropriate measures provided for in this Treaty.

Article 97

1. Where there is a reason to fear that the adoption or amendment of a provision laid down by law, regulation or administrative action may cause distortion within the meaning of Article 96, a Member State desiring to proceed therewith shall consult the Commission. After consulting the Member States, the Commission shall recommend to the States concerned such measures as may be appropriate to avoid the distortion in question.

2. If a State desiring to introduce or amend its own provisions does not comply with the recommendation addressed to it by the Commission, other Member States shall not be required, pursuant to Article 96, to amend their own provisions in order to eliminate such distortion. If the Member State which has ignored the recommendation of the Commission causes distortion detrimental only to itself, the provisions of Article 96 shall not apply.

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TITLE XIII

PUBLIC HEALTH

Article 152

1. **A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.**

Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education. The Community shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. **The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.** Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. **The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.**

3. The Community and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. **The Council, acting in accordance with the procedure referred to in Article 251** and after consulting the Economic and Social Committee and the Committee of the Regions, **shall contribute to the achievement of the objectives referred to in this article 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;
(b) by way of derogation from Article 37, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;
(c) incentive measures designed to protect and improve human health, excluding any harmonisation of the laws and regulations of the Member States.
The Council, acting by a qualified majority on a proposal from the Commission, may also adopt recommendations for the purposes set out in this article.
5. **Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care**. In particular, measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

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TITLE XVIII

RESEARCH AND TECHNOLOGICAL DEVELOPMENT

Article 163
1. **The Community shall have the objective of strengthening the scientific and technological bases of Community industry and encouraging it to become more competitive at international level, while promoting all the research activities deemed necessary by virtue of other chapters of this Treaty.**
2. For this purpose the Community shall, throughout the Community, encourage undertakings, including small and medium-sized undertakings, research centres and universities in their research and technological development activities of high quality; it shall support their efforts to cooperate with one another, aiming, notably, at enabling undertakings to exploit the internal market potential to the full, in particular through the opening-up of national public contracts, the definition of common standards and the removal of legal and fiscal obstacles to that cooperation.
3. All Community activities under this Treaty in the area of research and technological development, including
demonstration projects, shall be decided on and implemented in accordance with the provisions of this title.

Article 164
In pursuing these objectives, the Community shall carry out the following activities, complementing the activities carried out in the Member States:
(a) implementation of research, technological development and demonstration programmes, by promoting cooperation with and between undertakings, research centres and universities;
(b) promotion of cooperation in the field of Community research, technological development and demonstration with third countries and international organisations;
(c) dissemination and optimisation of the results of activities in Community research, technological development and demonstration;

(d) stimulation of the training and mobility of researchers in the Community.

Article 165
1. The Community and the Member States shall coordinate their research and technological development activities so as to ensure that national policies and Community policy are mutually consistent.
2. In close cooperation with the Member State, the Commission may take any useful initiative to promote the coordination referred to in paragraph 1.

Article 166
1. **A multiannual framework programme, setting out all the activities of the Community, shall be adopted by the Council, acting in accordance with the procedure referred to in Article 251** after consulting the Economic and Social Committee.
The framework programme shall:
— establish the scientific and technological objectives to be achieved by the activities provided for in Article 164 and fix the relevant priorities,
— indicate the broad lines of such activities,
— fix the maximum overall amount and the detailed rules for Community financial participation in the framework programme and the respective shares in each of the activities provided for.
2. The framework programme shall be adapted or supplemented as the situation changes.
3. **The framework programme shall be implemented through specific programmes developed within each activity.** Each specific programme shall define the detailed rules for implementing it, fix its duration and provide for the means deemed necessary. The sum of the amounts deemed necessary, fixed in the specific programmes, may not exceed the overall maximum amount fixed for the framework programme and each activity.
4. **The Council, acting by a qualified majority on a proposal from the Commission and after consulting the European Parliament and the Economic and Social Committee, shall adopt the specific programmes.**

Article 167
For the implementation of the multiannual framework programme the Council shall:
— determine the rules for the participation of undertakings, research centres and universities,
— lay down the rules governing the dissemination of research results.

Article 168
In implementing the multiannual framework programme, supplementary programmes may be decided on involving the participation of certain Member States only, which shall finance them subject to possible Community participation.
The Council shall adopt the rules applicable to supplementary programmes, particularly as regards the dissemination of knowledge and access by other Member States.

Article 169
In implementing the multiannual framework programme, the Community may make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes.

Article 170
In implementing the multiannual framework programme the Community may make provision for cooperation in Community research, technological development and demonstration with third countries or international organisations. The detailed arrangements for such cooperation may be the subject of agreements between the Community and the third parties concerned, which shall be negotiated and concluded in accordance with Article 300.

Article 171
The Community may set up joint undertakings or any other structure necessary for the efficient execution of Community research, technological development and demonstration programmes.

Article 172
The Council, acting by qualified majority on a proposal from the Commission and after consulting the European Parliament and the Economic and Social Committee, shall adopt the provisions referred to in Article 171. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee, shall adopt the provisions referred to in Articles 167, 168 and 169. Adoption of the supplementary programmes shall require the agreement of the Member States concerned.

Article 173
At the beginning of each year the Commission shall send a report to the European Parliament and to the Council. The report shall include information on research and technological development activities and the dissemination of results during the previous year, and the work programme for the current year.

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TITLE XX
DEVELOPMENT COOPERATION

Article 177
1. **Community policy in the sphere of development cooperation, which shall be complementary to the policies pursued by the Member States, shall foster:**
— the sustainable economic and social development of the developing countries, and more particularly the most disadvantaged among them,
— the smooth and gradual integration of the developing countries into the world economy,
— **the campaign against poverty in the developing countries**.

2. Community policy in this area shall contribute to the general objective of developing and consolidating democracy and the rule of law, and to that of **respecting human rights and fundamental freedoms**.
3. The Community and the Member States shall comply with the commitments and take account of the objectives they have approved in the context of the United Nations and other competent international organisations.

Article 178
The Community shall take account of the objectives referred to in Article 177 in the policies that it implements which are likely to affect developing countries.

Article 179
1. Without prejudice to the other provisions of this Treaty, the Council, acting in accordance with the procedure referred to in Article 251, shall adopt the measures necessary to further the objectives referred to in Article 177. Such measures may take the form of multiannual programmes.
2. The European Investment Bank shall contribute, under the terms laid down in its Statute, to the implementation of the measures referred to in paragraph 1.
3. The provisions of this Article shall not affect cooperation with the African, Caribbean and Pacific countries in the framework of the ACP-EC Convention.

Article 180
1. The Community and the Member States shall coordinate their policies on development cooperation and shall consult each other on their aid programmes, including in international organisations and during international conferences. They may undertake joint action. Member States shall contribute if necessary to the implementation of Community aid programmes.
2. The Commission may take any useful initiative to promote the coordination referred to in paragraph 1.

Article 181
Within their respective spheres of competence, the Community and the Member States shall cooperate with third countries and with the competent international organisations. The arrangements for Community cooperation may be the subject of agreements between the Community and the third parties concerned, which shall be negotiated and concluded in accordance with Article 300. The previous paragraph shall be without prejudice to Member States' competence to negotiate in international bodies and to conclude international agreements.

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PROVISIONS COMMON TO SEVERAL INSTITUTIONS

Article 249

In order to carry out their task and in accordance with the provisions of this Treaty, the European Parliament acting jointly with the Council, the Council and the Commission shall make regulations and issue directives, take decisions, make recommendations or deliver opinions. **A REGULATION shall have general application. It shall be binding in its entirety and directly applicable in all Member States. A DIRECTIVE shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods. A DECISION shall be binding in its entirety upon those to whom it is addressed. RECOMMENDATIONS and OPINIONS shall have no binding force.**

Article 250

1. Where, in pursuance of this Treaty, the Council acts on a proposal from the Commission, unanimity shall be required for an act constituting an amendment to that proposal, subject to Article 251(4) and (5).
2. As long as the Council has not acted, the Commission may alter its proposal at any time during the procedures leading to the adoption of a Community act.

Article 251 (Co-decision procedure)

1. Where reference is made in this Treaty to this Article for the adoption of an act, the following procedure shall apply.
2. The Commission shall submit a proposal to the European Parliament and the Council.
The Council, acting by a qualified majority after obtaining the opinion of the European Parliament: - if it approves all the amendments contained in the European Parliament's opinion, may adopt the proposed act thus amended, - if the European Parliament does not propose any amendments, may adopt the proposed act, - shall otherwise adopt a common position and communicate it to the European Parliament. The Council shall inform the European Parliament fully of the reasons which led it to adopt its common position.
The Commission shall inform the European Parliament fully of its position.
If, within three months of such communication, the European Parliament:
(a) approves the common position or has not taken a decision, the act in question shall be deemed to have been adopted in accordance with that common position;
(b) rejects, by an absolute majority of its component members, the common position, the proposed act shall be deemed not to have been adopted;
(c) proposes amendments to the common position by an absolute majority of its component members, the amended text shall be forwarded to the Council and to the Commission, which shall deliver an opinion on those amendments.
3. If, within three months of the matter being referred to it, the Council, acting by a qualified majority, approves all the amendments of the European Parliament, the act in question shall be deemed to have been adopted in the form of the common position thus amended; however, the Council shall act unanimously on the

amendments on which the Commission has delivered a negative opinion. If the Council does not approve all the amendments, the President of the Council, in agreement with the President of the European Parliament, shall within six weeks convene a meeting of the Conciliation Committee.
4. The Conciliation Committee, which shall be composed of the Members of the Council or their representatives and an equal number of representatives of the European Parliament, shall have the task of reaching agreement on a joint text, by a qualified majority of the Members of the Council or their representatives and by a majority of the representatives of the European Parliament. The Commission shall take part in the Conciliation Committee's proceedings and shall take all the necessary initiatives with a view to reconciling the positions of the European Parliament and the Council. In fulfilling this task, the Conciliation Committee shall address the common position on the basis of the amendments proposed by the European Parliament.
5. If, within six weeks of its being convened, the Conciliation Committee approves a joint text, the European Parliament, acting by an absolute majority of the votes cast, and the Council, acting by a qualified majority, shall each have a period of six weeks from that approval in which to adopt the act in question in accordance with the joint text. If either of the two institutions fails to approve the proposed act within that period, it shall be deemed not to have been adopted.
6. Where the Conciliation Committee does not approve a joint text, the proposed act shall be deemed not to have been adopted.
7. The periods of three months and six weeks referred to in this Article shall be extended by a maximum of one month and two weeks respectively at the initiative of the European Parliament or the Council.