

Project:
**The Landscape and Isobars of European Values in Relation to
Science and New Technology (Value Isobars)**

Project number:
230557

Title of deliverable*:
Science and Technology-Related Values and European law

Work package: 4

Authors:
Maria Eduarda Gonçalves

Maria Inês Gameiro

Partner (institution):
**DINÂMIA-CET – Center for Socioeconomic and Territorial
Studies**

ISCTE-IUL

Deliverable 1

Date: 07 February 2011

<u>1. Introduction</u>	<u>2</u>
<u>2. Values, legal principles and rights.....</u>	<u>5</u>
<u>3. Values in European law addressing science and technology</u>	<u>8</u>
<u>3.1. Balancing values, principles and rights in respect of biometrics</u>	<u>8</u>
<u>3.2. Balancing values, principles and rights in respect of human cloning.....</u>	<u>14</u>
<u>4. Comparing EU regulation of two technologies</u>	<u>17</u>

1. Introduction

Article 2 of the Treaty on European Union consolidated by the Treaty of Lisbon affirms that ‘The Union is founded on the **values** of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights, including the rights of persons belonging to minorities.’ Following up from this general declaration, Article 3 specifies EU’s fundamental objectives: first, an area of freedom, security and justice in which the free movement of persons is matched with appropriate border controls (n°. 2); second, an internal market based on balanced economic growth, a competitive social market economy and a high level of protection and improvement of the quality of the environment. An additional objective of the internal market is to ‘promote scientific and technological advance’ (n°. 3).

The explicit reference to *values* in the Lisbon Treaty stands for a novelty. However, reference to *liberty, democracy, respect for human rights and fundamental freedoms* is not an originality. The Treaty of European Union (Maastricht, 1992) embraced them under the reference to *principles* (Article 6). Adding the epithet of values (as guiding ideals, one might say) to these principles may be seen as a symbolic reinforcement of what already represented, with Maastricht, a breakthrough from the original Treaty of Rome establishing the European Economic Community (EEC) (1957). As a matter of fact, the objective of the EEC was primarily economic, i.e., the establishment of ‘a common market and an economic and monetary union’ (Article 1) and of common policies in the fields of agriculture, transports, and external trade (Article 3). In that context prevalence was assigned to *basic economic freedoms*, namely, the free circulation of workers and capital, free trade and the free establishment of enterprises in EEC’s territory.

Indeed, within the institutional framework of the post-II world war in Western Europe a kind of ‘division of labour’ had been laid down between the EC and the Council of Europe whereby the latter was attributed the function of guaranteeing the fundamental rights and freedoms of the

citizen by the means of a control of compliance of state parties to the Convention on Human Rights and Fundamental Freedoms (1950) while the former was mainly concentrated on market promotion. This does not mean to say that the early EEC was totally indifferent to the values of democracy and human rights. In reality, the EEC was created against the background of a democratic and human rights philosophical thought as Western Europe's common patrimony of social and political values. But it was not granted any specific competencies for action in this area. Priority was given for many decades to market-based objectives as shown, in particular, by the primacy of market 'freedoms' in the European Court of Justice's case-law.^{1 2}

Even after the entering into force of the Treaty of the European Union, in 1992, the scope of civil and political rights in the Treaty remained confined to *European citizenship* involving the rights to freedom to move and to reside within the territories of the member states (Article 2) and to participate in municipal elections in their member state of residence (Article 18). Only later, following the failed attempt to adopt a European Constitution and the subsequent adoption of the Treaty of Lisbon (2009) the way was paved for a true focus of EU political and legal discourse on **human values**. It is in this context that the Charter of Fundamental Rights of the EU was brought into life with binding force, even if not incorporated in the Treaty of Lisbon (Article 6 TEU).

No doubt, the Charter and the Treaty of Lisbon now offer a prime setting for the expression of the most prized *values* of Europe, meaning of course the European Union. Yet, while the adoption of the Charter with binding force should direct EU institutions in the design of law and policy, the question remains of how such effect will work in practice.

A domain falling under the EU's scope of responsibility in which respect for the Charter's values and principles is in this day and age especially critical is surely *science and technology*. *Scientific and technological advance*, as already pointed out, was proclaimed by the TEU as a key goal of the internal market. In turn, the Charter of Fundamental Rights states the EU intent 'to *strengthen the protection of fundamental rights in the light of changes in society, social progress and scientific and technological developments* by making those rights more visible in a Charter.' New scientific and technological advances such as inter alia genetically modified organisms, nanotechnologies, animal and human cloning, or security technologies have a bearing on moral and ethical values perceived by European societies as fundamental, including human dignity and integrity, as well as values typical of the contemporary post-industrial society such as environmental protection and consumer safety. All these values find expression in the Charter of Fundamental Rights in the form of *fundamental principles or rights*. It should also be recalled that, notwithstanding their equivalent status as

¹ See Curzon, 2009, p. 110 and 116, acknowledging the tendency of the ECJ to 'subordinate fundamental rights protection to the protection of fundamental economic freedoms', possibly related to the 'unbreakable bond between the European Court of Justice and the founding treaties which created it'. According to this author, even as it developed, timidly and slowly, protection of fundamental rights by the ECJ continued to be perceived as an exception to the general rule of market's fundamental freedoms (Curzon 2009, p. 122).

² In the EU context, human rights are most often referred to as 'fundamental rights.' No major conceptual difference is involved, and the terms will be used interchangeably in this report. The distinction between fundamental (human) rights (not listed in the Treaties) and fundamental (economic) freedoms (listed in the Treaties) is relevant, however. Some consider the economic freedoms to be human rights, but that is not the generally accepted view, see Bogdandy 2000, p. 1326.

principles of law and/or human rights, several of such principles and rights are amenable to collide with each other in theory as well as in concrete instances. Indeed, conflict or clash of rights is a familiar notion to the law, as is the proportionality principle that seeks to address this conflict (Tsakyrakis 2008). It seems, therefore, reasonable to ask how the new EU rhetoric focusing on human values might shape the legal and regulatory frameworks for scientific research and technological applications by looking at how the underlying balances of conflicting values, principles and rights have been addressed in the recent past.

Actually, in the last decades the main concern beneath EU regulation of scientific and technological development and innovation seems to have rested on prevention or precaution towards risk (namely, environmental, public health and safety risks) and only marginally on ‘other legitimate interests’ or ‘ethical concerns’ of society or individuals, despite the use of this kind of language in some regulatory instruments (Wynne et al. 2007).³ One issue thus is whether, and if so how, could the rising of human rights and related principles to statutorily fundamental guiding values of EU law change this trend.

The Charter has by now been regarded as an effort to make human rights ‘determine’ rather than simply ‘limit’ an EU legal system predominantly designed to guarantee market freedoms, implying a demand to the legislator and judiciary to ‘tilting the balance between regulatory policies and individual freedoms in favour of the latter’ (von Bodgandy 2000, p. 1321). It has also been argued, a process mirroring the construction of the internal market may be in the making for fundamental human rights: from ‘negative’ rights and freedoms implying the prohibition or limitation of certain acts to ‘positive’ rights and freedoms, in other words, ‘a comprehensive, coherent, balanced and forward-looking *human rights policy*’ (Alston and Weiler 1999, p. 8). Is this aim mere wishful thinking? To what extent is it being pursued, one might ask?

Against this backdrop, this report aims to *critically appraise how science and technology-related human or social values rendered explicit through the Charter’s principles and rights are being balanced against internal market values including the promotion of scientific and technological advance*. This appraisal will for the time being rely on the current EU legal framework for two novel technologies: *biometrics*, a new security technology whose development is being supported under the EU Research and Development (R&D) policy, and is employed mainly for individual and social surveillance purposes; and *cloning*, a biotechnology presently at an exploratory stage. Both biometrics and cloning, particularly human cloning, elicit complex, though distinct, ethical and legal challenges that have been addressed by European law lately. The selection of these technologies for

³ Legal instruments stating these concerns are among other Directive 2001/18/EC of 12 May (‘Respect for ethical principles recognised in a Member State is particularly important. Member States may take into consideration *ethical aspects* when GMOs are deliberately released or placed on the market as or in products’ (Recital 9, Directive 2001/18/CE of 12 March 2001)); Regulation 178/2002 of 28 January (‘It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors. (Recital 19)); and Directive 2005/28/EC of 8 April (‘Clinical trials shall be scientifically sound and guided by *ethical principles* in all their aspects’ (Article 2/3)).

the purposes of the present analysis lay on two main interrelated criteria: their controversial or contested nature that we take as an indicator of peoples' sensitivity or anxiety in that regard; and the extent to which they raise moral or ethical dilemma around basic values such as human dignity, individual autonomy, liberty or privacy. Our assumption is that the present state of affairs in the EU, where the design to promote scientific and technological progress goes alongside growing public fears about both ethical and social issues and potential adverse impacts of science and technology, underlines the need for a value-oriented framework for scientific and technological development and a value-based governance of science and technology.

The report will start by clarifying the key relevant concepts, values, principles and rights. Legal principles and human rights will provide the main entry points for our *review of values in EU S&T law and regulation* in respect of biometrics and human cloning, to be ascertained from a reading of the EU Charter on Fundamental Rights. This preliminary review aims to identify the values at issue, and how they relate or collide with each other: for example, Article 3 (Right to the integrity of human being) and the specific restrictions applicable to the fields of medicine and biology contained in the same article (e.g., the free and informed consent of the person concerned or the prohibition on making the human body and its parts as such a source of financial gain) may interfere with the freedom of the sciences guaranteed by Article 13; similarly, Article 8 on the right to protection of personal data may conflict with Article 16 on the right to conduct a business (or right to free enterprise). This right can be regarded as the legal background for technological and industrial innovation. The ways in which EU law and regulation are tackling these principles and rights, in theory and in practice, will be discussed in the light of the two examples selected.

2. Values, legal principles and rights

Values understood as standards of morality or justice and/or ends or ideals to be pursued enter the law through legal principles and legal rights. Many norms are or can be justified by values or high substantial principles such as justice or human rights.

Values, it has been suggested, may be approached through two consecutive steps: first, a reflection about values and, second, the definition of norms referring to those values and leading to rules, including legal rules (Mache 2006, p.34). Although values, principles and rules have been for a long time immersed in 'confusion and controversy' (Alexy 2010, p. 45), broadly speaking, law is essentially shaped by values: on a more general and abstract level, by law's intrinsic values of justice, equality and security, and on a more applied level by those that are codified through the choices of the legislator in each domain of policy or regulation. The former tend to be universal while the latter are evolving and changing, framed by a society undergoing permanent processes of adjustment, nowadays, in particular, to a 'new relationship between the law, science and technology' (Morin 2004, p. 94).

Values generally lead to principles translating into rights and from these to rules and regulatory instruments in a ‘series of interlocking definitions and distinctions’ (Dworkin 1977, p. 18). Such a ‘legal cascade’ thus flows from normative principles to ordinary law and case-law, as well as to soft-law instruments such as codes of conduct. Attention should be drawn to the fact that there is no rigid legal order hierarchy any longer. Different layers of principles and norms interrelate and influence each other. The general principles of law, especially those widely accepted by the EU and inserted in the Charter of Fundamental Rights, provide an illustration of this interaction (Habermas 2003, p. 127). In sum, law should be understood nowadays as more than a collection of rules of conduct imposed by the legislator and judges’ adjudication in the classic positivist definition. Particularly in the field of science and society the legal system involves a rising number of soft-law instruments, participatory mechanisms and advisory committees and panels.⁴

Yet, the definition of legal principles and legal rights is not always easy to make. Dworkin argued that principles are standards to be observed because they constitute requirements of ‘justice or fairness or some other dimension of morality’ (Dworkin 1977, p. 22). Habermas observed that while legal principles ‘have a deontological sense’, values that are embraced by the law are teleological (Habermas 1996, p. 255). In turn, Alexy defined principles as ‘norms commanding that something must be realized to the highest degree that is actually and legally possible’ (Alexy 1992, p. 145). Thus, the most obvious distinctive feature of a *legal* principle is its ‘juridical’ quality, opposing a merely ethical or social one, meaning that it must be included in a legal norm.

Legal principles, also conceptualised by some legal positivists as imperfect norms, provide general normative guidelines to be developed through legal norms, properly speaking (Zagrebelsky 2002, p. 870). Thus, both principles and norms are more or less general instructions with respect to expected behaviour of defined groups or the expected performance of a specific activity (Meisch and Potthast 2010, p. 3).

A deeply interrelated concept with that of legal principles is that of legal rights. *Legal rights* can be construed as freedoms to act or refrain from acting or entitlements to be acted upon or not acted upon that are provided by law. As societies become more complex, more and more rights, including freedoms, translate into obligations addressed to states or to third parties to ensure that their content is fulfilled. Hence both principles and rights as normative and authoritative statements translate particular values into goals for the legal order to achieve.

The EU Charter on Fundamental Rights offers a paradigmatic example of a human rights protection system that combines principles and rights (including freedoms). The singling out of *principles* and *rights* in the Charter can easily be ascertained from a simple reading.⁵ Indeed, one may

⁴ Accordingly, the notion of law used in this report will encompass both binding legal instruments of European law, i.e. regulations and directives of the European Council and the European Parliament and decisions of EU institutions; and soft law that is not formally binding and may emanate both from EU institutions and self-regulatory entities, for example, professionally-based codes of conduct.

⁵ Examples are Article 13, ‘The arts and scientific research shall be free of constraint’, and Article 37, ‘A high level of environmental protection and the improvement of the quality of the environment must be integrated into the policies of the Union and ensured in accordance with the principle of sustainable development’.

generally accept that when the Charter declares that specific values should be protected or specific goals should be pursued, it is asserting a principle, whereas when the individual is referred to by the Charter a right is being stated (Soares 2002, p. 69). Article 51/1 of the Charter, according to which EU institutions and Member States shall '**respect the rights**' and '**observe the principles**', while not differentiating these concepts neatly, renders clear the common responsibility of public authorities 'to promote the application' of both principles and rights. Further clarification comes out from the Explanations of the Charter (EU 2007b). Principles may be implemented through legislative or executive acts, and shape the ECJ and national court's interpretation or review of those acts, the document adds. However, they contrast with rights since they do not 'give rise to direct claims for positive action by the Union's institutions or Member States authorities'. This distinction between principles and rights should not be meant to imply that principles are weaker since European institutions are required to comply with such principles and can even be judicially responsible for not complying with them.

For the purposes of the present analysis, an additional distinction should be taken into account: law and regulation. While *law* can be identified with general and fundamental principles and rights, *regulation* is meant to be control exercised by a public agency over activities that are valued by a community. Public regulation involves policy choices and in that sense it represents a 'materialization of the law' (Habermas 1986). As indicated above, the legal order develops in a gradual manner from the initial generic framework set by principles and rights, normally stated in treaties and constitutions, progressively narrowed to public regulation. Public regulation typically entails the adoption of binding rules and the specification of powers deferred to the public administrations and in some cases to independent administrative authorities. In a wider, less technical assertion, regulation can also be understood as all forms of social control or influence, whether state-derived or socially-based (e.g. markets and civil society) (Baldwin and Cave 1999, p. 2). As pointed out already, regulatory institutions and procedures, e.g. for licensing or authorisation, and monitoring of certain economic or social activities, and the way regulatory competencies and powers are distributed among public bodies and other entities, both national and European, including the provision of consultative and participative mechanisms, may facilitate or otherwise constrain the receptiveness of the regulatory system to values as they are perceived in or by society.

The perception and the meaning of values for various individuals or groups, including for the legislator, are shaped by understandings about social justice and the right balance of public and private interests. Values, from a social standpoint, 'tend to be socially acceptable 'good reasons'', are socially shared and socially binding (Gaskell et al. 2010, pp. 1-2). Hence, while assessing the translation of values into European law and regulation attention should be paid to the channels opened by law for stakeholders and civil society to have a say in the regulatory process and by this means expressing 'their' most-prized values and ultimately shaping the value system brought into law or regulation. To what extent are there 'platforms of dialogue on values', as recommended by the European Commission (EC 2005, p. 20)?

In this connection, one might recall the observation of Habermas that modern ‘material’ law can no longer rely exclusively on substantive norms; it requires a procedural justification as the basis for its social legitimacy (Habermas 1986). Growing attention to regulation of procedures beyond substantive regulation has indeed been seized by Teubner as a progressive trend (Teubner 1996)⁶.

3. Values in European law addressing science and technology

As pointed out already, principles and rights provide us with the main doorways for acceding to values embedded in the law. Principles play a critical role in respect of emerging sciences and technologies since they can more easily accommodate the dynamics of scientific and technological progress. An example of such a principle contained in the EU Charter might be the principle of sustainable development (Article 37). The downside of this option is that less rigidity normally equals less binding force in practice since a large scope for interpretation is left open. Yet, in a few instances, the Charter itself is quite strict, an illustration being the prohibition of the reproductive cloning of human beings guaranteed under the right of the integrity of the person (Article 3).

Since the protection of individual or groups’ rights is carried out through principles and norms that are likely to limit or constrain scientific activities or the development or employment of technology, there is scope for conflict between the interests or rights of S&T developers and users and those of individuals or society. The EU legislator often seeks to balance these opposing interests and rights, namely, research and technological development understood as an interest of the EU and the rights of individuals or citizens. Often, this contradiction is presented as opposing ethical to market values. But the issue is more complex than that. The freedom of research, for example, may be regarded as a component of the fundamental freedoms of thought and of speech; yet, it may also be related with free enterprise.

Against this background, which values are being summoned by European law and regulation shaping the development and deployment of biometrics and human cloning, one may ask? Beyond the general provisions of the Charter of Fundamental Rights, how are conflicting principles and rights being tackled by EU regulation? And what does that tell us about the ‘value system’ embedded in European law on science and technology (S&T) more generally?

3.1. *Balancing values, principles and rights in respect of biometrics*

Biometrics is a technique that relies on human characteristics to verify the identity of an individual. Face features, fingerprints, hand impressions, iris recognition or DNA are such

⁶ In respect of bioethics, the observation has been made that institutionalization of this field is increasingly political, not because that would be different than moral bioethics, but precisely because its way of ‘making morality’ in the public sphere draws its relevance more and more from the incorporation of procedures into the institutions (Picavet 2000).

physiological features that can be used in biometrics. Biometric technology can thus be defined as identifying individuals by using their biological or behavioural characteristics.⁷

Lately biometric technology turned out to be one of the central pieces of national and international security and immigration policies in Europe and is becoming also increasingly important economically as it is more and more employed to control access of workers, students, and other categories of people in various organisations (IPTS 2005, p. 80-87). This technology rose to the centre of techno-judicial and techno-political debates of our era following the '9/11' when security measures became more tightened worldwide approaching the idea of a 'maximum security society' (Marx 1988).⁸

Liberty, security and privacy are the most obvious values challenged by biometrics. But others are at stake as well, namely dignity and democracy. In fact, alongside the growing use of biometrics, concerns about civil liberties and the values underneath have amplified. The dichotomy between security, on one hand, and freedom, privacy and even human dignity, on the other, as well as the classic and broader confrontation between security and democracy came up in that connection.

As a matter of fact, the growing use of information and surveillance technologies brings about a higher degree of complexity of value conflicts, and maybe even novel value conflicts. According to De Hert (2005b, p. 38), 'there is a need to establish both common principles and language of privacy for biometrics, including principles such as equality of access to the network; absolute accuracy of targeting by surveillance systems; systems to ensure the accuracy of the data held within the surveillance systems; mechanisms for making good the bad, inaccurate or changed data; systems to protect individuals from their inclination to trade their own privacy'. Some authors have called attention to a maybe upcoming 'surveillance society' largely nurtured by unawareness of citizens themselves about the corresponding risks (Marx 2008). They fear that the current legal system may give too much leeway to new technological developments incepted without proper interrogation from and altering to a human rights perspective.

When collecting the biometrical data, the physical integrity of the subject should be secured against any harm, it has also been argued. Beyond privacy, intimacy and the emotional integrity of the person together with the dignity and respect for the person's 'decorum' need to be considered as well (CNPD 2004, p. 2). Biometric characteristics represent a part of people's individuality and are intimately linked to the persons themselves (CNPD 2004, p. 1).

Hence the values interfered with by biometrics can be divided in two sets: security and related rights, on the one hand, and liberty, privacy, intimacy and related rights (namely, data protection), on the other. The right to conduct a business and the freedom of research also play a part in the

⁷ Physiological and behavioural characteristics (voice, signature, etc.) are sometimes differentiated as biometrical indicators, but the distinction is not a peaceful one.

⁸ This comes out from a number of EU documents such as the proposal of September 2003 on a uniform format for visas and residence permits and the proposal of February 2004 for a regulation on biometrics in EU citizens' passports, COM(2004) 116 final. However, it has also been pointed out that the 9/11 justification fails partly since most of the terrorists travel with their own valid passports (Hornung 2007, p. 259).

biometrics' 'rights balance' to the extent that development and economic investment in biometric technologies are recognised as legitimate rights.

Security along freedom has always been an ideal of human societies, portrayed by Hobbes as an essential value (Hobbes 2008). But security can mean protection provided by the state and protection from the state. Both meanings have their limits and privacy and dignity play an important role in defining those limits. Privacy also involves a variety of meanings and needs to be balanced against related concepts such as intimacy and anonymity.

However, the official European stance on this complex matter rests on the assumption that security and civil liberties can be easily compared and conciliated (Liberatore 2007, p. 114). The paradox may be, though, that 'surveillance techniques (...) were developed as means of granting civil rights and, at the same time, serve as potential means for states to gain informational power over citizens' and, ultimately, to limit civil rights' (Liberatore 2007, p. 113). The argument has also been built around the idea that biometrics can be used to guarantee privacy (when used to reduce the access of a room or a computer through a fingerprint recognition technique to a single person for instance) countering the idea 'more security, less privacy' (Hornung 2007, p. 249).

Article 6 of the Charter goes even further in this conciliatory move since it addresses *liberty and security* as part of a *unique right*. Yet, this 'right to liberty and security' raises a number of questions: why have liberty and security been treated in an integrated manner in the Charter? Should they be regarded as the two faces of the same coin or rather as conflicting principles or rights?⁹

In fact, the single right option was not free from controversy during the negotiations which led to the adoption of the Charter. There were proposals to separate both concepts and proposals to delete the reference to 'security' that did not come through mainly because this is the phrasing of the European Convention of Human Rights.¹⁰

Also 'privacy and data protection should not be characterised as a zero sum gain where an individual gain means a societal loss or vice-versa', it is stated in a report published by the EC (Robinson et al. 2009, p. 16). This idea has been underlined in other policy documents reflecting the European perspective: opposing an individual value such as liberty against a rather more community-oriented value such as security does not necessarily mean that an individual value is being sacrificed in the name of the society – in fact, instead of a 'zero sum game' the official description points to a 'win-win' situation. This understanding has reminiscences with the theoretical approach considering rights and policies to be, not exclusive, the first concerning the individual and the second society (Dworkin 2002, p. 23), but interchangeable concepts instead (Atienza 1991, p. 106).

One may possibly intuit that the 'single right' option may have been part of a political stratagem to render a novel EU security policy more acceptable to the public opinion. Referring to the 'rush' to using biometrics within Europe, a EC-sponsored report noted, 'The driving force has of

⁹ Biometrics raise other issues, namely: concerns for power accumulation, and about further use of existing data; concerns about specific threats proper to biometrics; about the use of this technology in the private sector and about the inability to protect individuals from their inclination to trade their own privacy and concerns for costs (De Hert 2005, p. 37; Marx 2008).

¹⁰ Charte 4360/00, Convent 37, p. 8.

course been entirely political and aimed at demonstrating some sort of response to terrorism and national security, while simultaneously introducing vastly increased powers of law enforcement activity.’ (Ashbourn 2005, p. 20). The same conclusion can be drawn from the active promotion of biometrics in EU research and development policy. Decision N° 1982/2006/EC approving the 7th Framework Programme follows the same direction stating that ‘security in Europe is a *precondition of prosperity and freedom*’.¹¹ The 7th Framework Programme for R&D (2007/2013) includes a specific chapter on security technologies as one of the ten themes for Community action where the objective is ‘to develop the technologies and knowledge for building capabilities needed to ensure the security of citizens from threats such as terrorism, natural disasters, and crime, while respecting fundamental human rights including privacy’.¹² Among these technologies are the ones related with ‘intelligent surveillance and border security’, including ‘methods for rapid identification required for improving the security of Europe's land and coastal borders, including border control and surveillance issues’.

A ‘security and society’ theme was included in this research programme, designed to be present through all the security research and development areas as a ‘mission orientated research which will focus on socio-economic analyses, scenario building and activities related to: cultural, social, political and economic dimensions of security, communication with society, *the role of human values and policy making*, psychology social environment of terrorism, citizens' perception of security, ethics, protection of privacy, societal foresight and systemic risk analysis’.

A look at the legal framework applicable to the employment of biometrics in EU law leads us to two results only: Council Regulation (EC) N° 2252/2004 of 13 December 2004 on standards for security features and biometrics in passports and travel documents issued by Member States; and Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, which is rendered applicable with regard to the personal data to be processed in the context of passports and travel documents by Regulation N° 2252/2004 (Article 4 and Whereas 8).

Remarkably, Regulation N° 2252/2004 is basically a technical normative text, rather than a value or rights-oriented one.¹³ Its object centers on the technical specifications and standards for passports and travel documents, which the regulation seeks to harmonise across the EU. Yet, the right to security is somehow privileged given the emphasis placed on biometrics as a requisite for more secure and reliable identification of holders and protection against falsification or other fraudulent use.

From the fundamental human rights’ angle the European legislator has limited its consideration to biometrical data protection, thus disregarding the implications of the employment of biometrics on the individuals’ intimacy component of privacy and on the exercise of freedom and democracy more generally. As a background paper for the IPST courageously acknowledges,

¹¹ Decision N° 1982/2006/EC, L412/26.

¹² In the 7th Framework Programme from a total of 50 521 million euro, 1400 went to the ‘Security area’ (Decision N° 1982/2006/EC, Annex II).

¹³ Article 1 of Regulation N° 2252/2004, amended by Regulation N° 444/2009.

‘principles of privacy and data protection have been discarded wholesale.’ And, the report goes on, ‘if we are not careful, we shall find ourselves headed towards a global police state, heavily manipulated by one or two strong governments. This will not make for a better world.’ (Ashbourn 2005, p. 20-21)

Conceiving security and freedom as merged into one single right no doubt helps reducing the scope for these rights’ conflict. Potential consequences of spread of the use of surveillance technologies for democracy also tend to be presented in EU political discourse on a positive, rather than negative tone, i.e., security technologies being portrayed as a means to protect our democratic systems against external threats. However, as the same IPTS background paper audaciously notes, ‘if we continue blindly along this path, where will it take us in 10, 20 and 30 years from a societal perspective?’ (Ashbourn 2005, p. 20)

In reality, biometrics is, in our view, at the centre of an actual conflict opposing *liberty* in the sense of free movement of persons or security as it implies strengthened border or other controls of people. Moreover, growing use of biometrics as a surveillance technology risks impinging on important personal values such as privacy and intimacy, as well as affect the workings of democratic and free societies given the behavioural constraints that it may further. In his Opinion delivered on the Case C-137/05, Advocate General Trstenjak acknowledged the problems raised from the fundamental human rights’ angle by Regulation (EC) N° 2252/2004 on the harmonisation of the security features including biometric identifiers for the passports and travel documents¹⁴. However, since in the judicial process the United Kingdom did not challenge the regulation on grounds of human rights violation, the Court was not offered an opportunity to consider this matter. In turn, the European Data Protection Supervisor also recognised that ‘there can be no doubt about the importance of a strong mechanism for the protection of fundamental rights of the citizen’ regarding biometrics.¹⁵

EU regulation of biometrics thus emphasises personal data protection.

The biometrical process involves capturing and collecting ‘information relating to an identified or identifiable natural person’ which is one ‘who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity’, according to the EU data protection directive (Directive 95/46/EC, Article 2, a.). Therefore, data protection represents an important facet of biometrics technology’s regulation.

As applying the data protection regime to biometrical data as to any other category of personal data implies the presumption of the legitimacy of biometrics. Besides, data protection legislation allows the data processor to be the first arbiter of the need to process biometrical data, raising doubts about how the requirements of procedural justice are tackled. In this respect, the

¹⁴ Opinion of Advocate General Trstenjak, delivered on 10 July 2007, Case C-137/05, United Kingdom v Council of the European Union [2008] ERC I-02245, paragraph 126.

¹⁵ Opinion of the European Data Protection Supervisor on the Communication from the Commission to the European Parliament and the Council on an area of freedom, security and justice serving the citizen (2009/C 276/02), p. 9.

Article 29 Data Protection Working Party, acknowledging the increasing collection of biometrics, considers that biometrical data should only be used in a subsidiary way, that is, whenever 'less intrusive material' does not allow the same effect (Article 29 Data Protection Working Party 2009, p. 27).¹⁶

Directive 95/46/EC balances between different policy goals, interests and rights, namely those of public or private organisations in the use of personal data, and those of the data subjects in the good use and protection of such data. The data controller must ensure compliance with a series of principles, including the principles of data quality and the principle of transparency (Article 6). These principles echo in the Regulation in Article 4, 2 and 3.

The data subjects have the right to know who the data controller is, the purpose of the processing, the recipient of the data and to have inaccurate data rectified (Articles 10 and 11). The directive contains strengthened protections concerning the use of *special categories of personal data* relating namely to racial or ethnic origin, religious or philosophical beliefs, health and sex life (Article 8). Biometrical data may be regarded nowadays as an additional category of personal data deserving special protection given their hypersensitive character.

However, the right to personal data protection may be restricted in order to safeguard national security, defence, public security, prevention and criminal investigation, economic or financial interests of states, rights and freedoms of others (Article 13). This is in line with Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms that addresses the potential conflict between the right to privacy and the public interest, allowing that the right to privacy (as well as to family life, his home and correspondence) may be interfered with by a public authority 'in accordance with the law' when 'necessary in a democratic society in the interests of *national security*, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.'

The security exception is stirring recent developments of EU policy. In March 2010, the EC presented a 'Proposal of a Regulation for the creation of an Agency for the operational management of large-scale IT systems in the area of freedom, security and justice' covering matters related to checks on persons at external borders, illegal immigration and illegal residence and asylum.¹⁷ But the European Parliament raised doubts about the ensuing perils for human rights (EP 2005).

In sum, biometrics has been mostly framed by the EU in light of security values, and related principles and rights, to the detriment of the consideration of its implications for the exercise of freedom and democracy. The insufficiency of the procedural arrangements from the point of view of social involvement in this respect has been observed:

¹⁶ The EU Charter of Fundamental Rights clarifies the status of the protection of personal data as a fundamental right. Besides, Article 16 of the Treaty on the Functioning of the European Union extends the implementation of the data protection principles and rights to EU institutions. Will this raising of the rights to privacy and data protection to a fundamental right status may affect their balance vis-à-vis the rights of data controllers, one may wonder.

¹⁷ COM (2010) 93 final, 19.03.2010.

'It is time also to bring citizens squarely into the debate. Not by carefully manipulated opinion polls, but by honest and open public discussion. In this report, we have made some strong points and offered views contrary to what some might perceive as being politically correct, and quite deliberately so. The dialogue to date has been heavily influenced by commercial interest and political aspirations. There has been remarkably little genuine consultation with citizens on a matter which will have a significant impact upon society.' (Ashbourn 2005, p. 21).

By the same token it is being recognised that existing data protection rules on the use of biometrics 'lack normative content and ethical debate' (IPTS 2005, p. 16), thus paving the way for a reconsideration of the current legal framework for biometrics.

3.2. Balancing values, principles and rights in respect of human cloning

Cloning, a technology still at an experimental stage, is one of the most controversial issues in the bioethics debate nowadays; a debate that is far from being closed.

'Cloning is the process of producing 'genetically identical' organisms. It may involve division of a single embryo, by prompting a fertilised egg to split in two, in which case both the nuclear genes and the small number of mitochondrial genes would be 'identical', or it may involve nuclear transfer, in which case only the nuclear genes would be 'identical' (GAEIB 1997, p. 2). This distinction is relevant in considering the implications of cloning, namely human cloning (GAEIB 1997, p. 4). The first method is the simpler way to create a clone. This is a technique already employed for stock breeding that constitutes with somatic cell nuclear transfer the main techniques of reproductive cloning, or simply put, the use of technology to create a living copy of an existing human. The second method, cloning by nuclear replacement, or therapeutic cloning, is a technology whereby embryonic stem cells can be harvested for curing diseases and eventually to replace organs and tissues. Considering human implications, while reproductive cloning allows theoretically for the creation of new human lives, therapeutic cloning allows just for the creation of new tissues and organs from human stem cells.

According to the Group of Advisers on the Ethical Implications of Biotechnology of the European Commission, therapeutic cloning or non-reproductive cloning, limited to the in-vitro phase, and reproductive cloning should be distinguished. Some countries oppose one and not the other, others ban cloning altogether and others do not have a clear position or legislation on these matters¹⁸. But for the European Parliament: 'there is no difference between cloning for therapeutic purposes and cloning for the purposes of reproduction' and 'any relaxation of the present ban will lead to pressure for further developments in embryo production and usage'.¹⁹ For the Parliament, "therapeutic cloning", which involves the creation of human embryos solely for research purposes, poses profound ethical dilemma, irreversibly crosses a boundary in research norms and is contrary to

¹⁸ See Annex 2.

¹⁹ European Parliament Resolution on Human Cloning, paragraph H.

public policy as adopted by the European Union”.²⁰ Though supporting the funding of embryonic stem cell research, the EU banned the funding of research on human cloning.²¹

Indeed, human cloning, deliberately to produce genetically identical human beings, raises serious ethical issues with respect to human dignity and possible manipulation of the human being. On the one hand, research involving human nuclear transfer could have important therapeutic implications, for example the development of appropriate stem cell cultures for repairing human organs. It could also provide insights into how to induce regeneration of damaged human tissues’ (GAEIB 1997, p. 5).

Yet, on the other hand, various arguments, including ethical and social, and technical arguments, have been advanced to support the ban on reproductive cloning:

a. ‘the visceral reaction that many in the public have had to the idea of human reproductive cloning is, from a policy perspective, significant enough to justify, on its own, a regulatory response’;

b. ‘reproductive cloning would have an adverse impact on the social definition of family: ‘modernity’s assault on the family would thus be complete with the development of cloning. Already stripped of its social function, the family would now be rendered biologically unnecessary, if not irrelevant’;

c. ‘clear health and safety issues that are far from being resolved (...), the possible health risks associated with reproductive cloning’; and

d. ‘human reproductive cloning, at some level, infringes notions of human dignity’ (Caulfield 2003, p. 2).

Arguments based on human dignity generally differentiate matters of autonomy (the uniqueness of each human being), instrumentalism (the idea that human beings should always be treated as ends, not as means), replication (condemning replication opposed to reproduction) and community or communal dignity, making the human genome symbolically a part of the heritage of humankind (as stated in the UNESCO Universal Declaration on the Human Genome and Human Rights, 1997, Article 1). Another set of arguments frequently put forward against human cloning include: security (genetic research can pose great danger), social justice (the costs of the technology would make it affordable only to the very rich) and aesthetics (the world would have less variety since everyone would want to have more or less similar desired characteristics) (Dworkin 2002, p. 439). This last ground relates to the notion of detached values, the ones that constitute intrinsic characteristics of objects or events (Dworkin 2002, p. 428).

Some of the difficulties raised by human cloning go deeper to the point of defining human identity (related with the uniqueness of each person), a concept that some argue, is often confused with genomic identity. Human identity can be said to be a more complex notion (including cultural and social environment) than genomic identity (Feuillet-Le Mintier 2006, p. 125). Ultimately, at the

²⁰ European Parliament Resolution on Human Cloning, paragraph 2.

²¹ European Parliament Resolution on Human Cloning, paragraph E.

core of the debate on human cloning and the values that it touches upon lies the very definition of man (Feuillet-Le Mintier 2006, p. 121).

Human cloning has been addressed by the EU at the highest political level, by a European Parliament resolution, grosso modo by the time the Charter of Fundamental Rights was first adopted, including a specific principle on this matter.

While recognising that ‘the undoubted need for medical research resulting from advances in knowledge of human genetics must be balanced against strict ethical and social constraints’²², the European Parliament resolution on human cloning, approved in 2000, proclaimed that ‘there should be a universal and specific ban at the level of the United Nations on the cloning of human beings at all stages of formation and development’²³. To justify this ban, the European Parliament’s resolution emphasised the value of ‘human dignity and the consequent value of each human being’²⁴.

The EU Charter of Fundamental Rights eventually prohibited the reproductive cloning of human being (Article 3, paragraph 2, d). That ‘human dignity is inviolable’ is also affirmed by the Charter (Article 1).

However, the human dignity argument can be erroneous, Caulfield alerted, while calling attention to ‘the lack of thoughtful *policy analysis* of the role of human dignity’ that ‘hurts the broader public debate about reproductive cloning, trivializes the potential value of human dignity as a normative principle and makes it nearly impossible to critique the actual justifications behind many of the proposed policies’ (Caulfield 2003, p. 2).

In fact, it is not easy to deal with the conceptual ambiguity around the notion of human dignity, and its nature as a right or as a principle. The EU Charter does not clarify these doubts, but the preparatory Convention discussed extensively the need to recognise human dignity in the first article of the Charter, ‘not only a fundamental right in itself but the real basis of fundamental rights’.²⁵ Another important reflection revolves around the autonomous utilization of human dignity as a normative concept in legal disputes, namely by the ECJ and the European Court of Human Rights. The first one dealt with the question of human dignity in the Case C-377/98 opposing Netherlands and the Commission concerning the protection of biotechnological inventions from patenting. Netherlands, supported by other countries, maintained that Directive 98/44/EC undermined human dignity allowing the patenting of parts of the human body. The Court never addressed the concept of human dignity in spite of using it profusely²⁶. In the same case, the Advocate General affirmed that the ‘human body is the vehicle for human dignity’.²⁷ This approach relates directly not only human cloning but also biometrics.

Here again a look at the procedures followed to set up the EU legal framework of human cloning is needed in order to better understand the underlying value choices in view of how decision-

²² European Parliament Resolution on Human Cloning, paragraph B.

²³ European Parliament Resolution on Human Cloning, paragraph 10.

²⁴ European Parliament Resolution on Human Cloning, paragraph A.

²⁵ Charte 4471/00, Convent 48, p. 3

²⁶ Case C-377/98, paragraph 69 – 81.

²⁷ Opinion of Advocate General Jacobsen, Case 377/98, paragraph 190.

making powers are distributed, as well as of who is heard or consulted. The Convention that drew the Charter prohibited human cloning altogether instead of just reproductive human cloning in the beginning of the preparatory work.²⁸ The specification of reproductive human cloning came in the process²⁹, although there were some requests to maintain the general prohibition.³⁰ Several documents underline the fact that the list in n°. 2 of Article 3 is not an extensive one. Probably in an attempt to avoid the controversy surrounding the division between principles and rights mentioned before, the phrasing ‘in the fields of medicine and biology, the following *principles* must be respected’ that corresponds to the early drafts of the Charter changed and, latter, the word principles disappeared from the adopted formula.³¹

That the EU has limited itself for the time being to declare a general principle of prohibition of human cloning signals the fact that, unlike biometrics, human cloning is not in the process of being applied in practice. Yet, the future of this technology is hardly predictable.

4. Comparing EU regulation of two technologies

Both biometrics and human cloning raise critical challenges from the ethical standpoint and by the same token an opportunity to scrutinize the principles and fundamental rights that have been designed to frame their use and the underlying values.

At a preliminary glance, the reading of the two main European documents – the European Convention for the Protection of Human Rights and Fundamental Freedoms and the European Charter of Human Rights – already indicates two different approaches, both in the documents and the technologies. On the subject of biometrics Article 8 of the Convention allows for restrictions in the right to privacy, pointing to the necessity of balancing and value judgements – the previously mentioned necessity in a ‘democratic society’ (Article 8) (Hert 2005a: 80). On the other hand, the Charter states both the prohibiting of human cloning (Article 3) and the right to privacy concerning the protection of personal data (Article 8) without exceptions.

As pointed out, current EU law addresses human cloning through an absolute prohibition based on consideration of the *fundamental nature* of the values at stake, first of all *human dignity*, believed to deserve higher weight than research freedom or social rights like the right to health. In contrast, biometrics’ use has been declared legitimate and the EU is even encouraging its development under its framework programme for research and development, as seen above. While funding biometrics research may be subject to ethical criteria, a general rule of the framework programme, biometrics applications are framed by specific EU regulation, namely on the biometrical passport, and on personal data protection. The balancing of conflicting values, principles and rights,

²⁸ Charte 4123/1/00, Convent 5, p. 4.

²⁹ Charte 4371/00, Convent 38, p. 4 the wording ‘reproductive cloning’ already appears.

³⁰ Charte 4360/00, Convent 37, p. 5.

³¹ Charte 4284/00, Convent 28, p. 4.

is therefore required. While in the letter of this legislation, none should prevail over the other (this is the idea itself of balancing), the question remains of how in reality such balancing works.

The introduction of biometrics in passports and travel documents in the EU was, as pointed out, a consequence of a political decision adopted under pressure by the USA, already engaged in the 'war on terror'. Once that political decision had been taken, the EU pursued its conventional, somewhat instrumental path towards technical standards harmonisation. Introducing biometrics as such did not raise a specific problem from the human rights' viewpoint. Human rights considerations were formatted as a *personal data protection* issue similar to that of other data digital applications to be addressed under an existing legal framework.

Human cloning as a technology which directly interferes with highly prized human values, namely, human integrity and human dignity, appears to bear a stronger protection than biometrics, a surveillance technology that affects the sphere of human liberty, and indirectly, people's feelings or sentiments as well. This divergence needs to be explored in a more in-depth manner.

In both technologies there are tensions between the Commission and the European Parliament. In the biometrics case the intervention of the Parliament guaranteed the requirement to secure the confidentiality and the lawful purposes of the data but didn't guarantee the request of the involvement of the Article 29 Data Protection Working Party in the process. However, in the human cloning case the only legal document produced came from the European Parliament.³² The question of the frontiers between ethics and the law, and between ethical values and legal principles comes out in this connection. In fact, ethically-based reports, charters or committees, despite their important intrinsic importance, lack the element of bindingness (Feuillet-Le Mintier, 2006: 127). Being an area where the ethical dimensions are crucial, human cloning also features a technology subject to a ban with the ensuing legal consequences for disobeying.

On a formal note, we can observe that the number of legal instruments concerning both technologies is limited, as opposed to the number of policy documents and group reports, also referred to as the 'infra-droit' (Feuillet-Le Mintier 2006, p. 126).

³² A number of documents demonstrate this tension. See COM 2004(116) and the European Parliament legislative resolution on the proposal for a Council regulation on standards for security features and biometrics in EU citizens' passports. See also Hornung 2007, p. 255.

References

Alexy, Robert (2010), *A Theory of Constitutional Rights*. Oxford: Oxford University Press.

Alexy, Robert (1992), 'Rights, Legal Reasoning and Rational Discourse', *Ratio Juris*, vol. 5, n. 2, pp. 143-152.

Alston and Weiler (1999), "An 'ever closer union' in need of a human rights policy", in Alston (Ed.), *The EU and Human Rights*. Oxford: Oxford University Press.

Article 29 Data Protection Working Party (2009), 'The Future of Privacy, Joint contribution to the Consultation of the European Commission on the legal framework for the fundamental right to protection of personal data', 02356/09/EN, WP 168, adopted on 1 December 2009.

Ashbourn, Julian (2005), 'The Social Implications of the Wide Scale Implementation of Biometric and Related Technologies', Background paper for the Institute of Prospective Technological Studies, DG-JRC, Sevilla, European Commission, http://cybersecurity.jrc.ec.europa.eu/docs/LIBE%20Biometrics%20March%2005/SocialImplications_Ashbourn.pdf.

Atienza, Manuel; Juan Ruiz Manero (1991), 'Sobre principios y reglas', in *Doxa: Cuadernos de Filosofía del Derecho*, 10, pp. 101-120, http://www.cervantesvirtual.com/servlet/SirveObras/12482196462352624198846/cuaderno10/doxa10_04.pdf.

Baldwin, Robert and Martin Cave (1999), *Understanding Regulation. Theory, Strategy and Practice*. Oxford: Oxford University Press.

Caulfield, Timothy (2003), 'Human cloning laws, human dignity and the poverty of the policy making dialogue', *BMC Medical Ethics*, No. 4, 29 July 2003, <http://www.biomedcentral.com/content/pdf/1472-6939-4-3.pdf>

CNPD - Comissão Nacional para a Protecção de Dados (2004), Parecer 'Princípios sobre a utilização de dados biométricos no âmbito do controlo de acessos e de assiduidade', <http://www.cnpd.pt/bin/orientacoes/principiosbiometricos.htm>.

Comité Consultatif National d'Ethique pour les Sciences de la Vie et de la Santé (2007), 'Biométrie, données identifiantes et droits de l'homme', Avis n° 98, 20/06/2007.

Comité Consultatif National d'Ethique pour les Sciences de la Vie et de la Santé (2007), 'Questions éthiques posées par les nanosciences, les nanotechnologies et la santé', Avis n° 96, 07/03/2007.

Comité Consultatif National d'Ethique pour les Sciences de la Vie et de la Santé (2007), 'Avis sur la constitution de collections de tissus et organes embryonnaires humains et leur utilisation à des fins scientifiques', Avis n° 52, 11/03/1997.

Comité Consultatif National d'Ethique pour les Sciences de la Vie et de la Santé (2007), 'Avis sur la constitution de collections de cellules embryonnaires humaines et leur utilisation à des fins thérapeutiques ou scientifiques', Avis n° 53, 11/03/1997.

Comité Consultatif National d'Ethique pour les Sciences de la Vie et de la Santé (2007), 'Réponse au Président de la République au sujet du clonage reproductif', Avis n° 54, 22/04/1997.

Council of Europe (1998), Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, Paris.

Council of Europe (1950), Convention for the Protection of Human Rights and Fundamental Freedoms, Rome.

Council of Europe (1981), Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, Strasbourg.

Council of Europe (1997), Convention on Human Rights and Biomedicine, Oviedo.

Council Regulation (EC) N° 2252/2004 of 13 December 2004 on standards for security features and biometrics in passports and travel documents issued by Member States.

Curzon, Stephen (2009), 'Fundamental rights and the Internal Market. The state of affairs following Schmidberger & Omega', in *Les droits fondamentaux dans l'Union européenne*, Joël Rideau (dir.), Bruxelles: Bruylant, pp. 109-129.

Directive 95/46/EC of the European Parliament and the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

Dworkin, Ronald (2002), *Sovereign Virtue, The Theory and Practice of Equality*. Cambridge: Harvard University Press.

Dworkin, Ronald (1977), *Taking Rights Seriously*. London: Duckworth.

European Commission (2003), Commission Staff Working Paper, 'Report on Human Embryonic Stem Cell Research', SEC(2003) 441, 03/04/2003

European Commission (2009), *Challenging Futures of Science in Society, Emerging Trends and cutting-edge issues*, Report of the MASIS Expert Group. Brussels: European Commission. ftp://ftp.cordis.europa.eu/pub/fp7/sis/docs/sis_masis_report_en.pdf

European Commission (2004), Proposal for a Council Regulation on standards for security features and biometrics in EU citizens' passports, COM(2004) 116 final.

European Commission (2005), *Social Values, Science and Technology*. Report of the Science Policy Research Group (Coord. G. Gaskell). Brussels: European Commission.

European Data Protection Supervisor (2009), 'Opinion on the Communication from the Commission to the European Parliament and the Council on an area of freedom, security and justice serving the citizen', 2009/C 276/02.

European Parliament (2005), Resolution on the proposal for a Council regulation on standards for security features and biometrics in EU citizens' passports, *Official Journal* 2005 E , 25/08/2005 P. 0050 – 0054

European Parliament (2000), Resolution on human cloning (7 September 2000).

European Union (2007a), Charter of Fundamental Rights of the European Union, 2007/C 303/01.

European Union (2007b), Explanations relating to the Charter of Fundamental Rights, 2007/C 303/02.

Feuillet-Le Mintier, Brigitte (2006), 'Un exemple de prohibition: la recherche sur le clonage humain', in Isabelle de Lamberterie, Étienne Vergès (dir.), *Quel Droit Pour La Recherche?*, Paris : LexisNexis, pp. 119-130.

Galand, Olivier e Yannick Lemel (2007), *Valeurs et Cultures en Europe*. Paris: La Découverte.

Gaskell, George, *et al.* (2010), 'Value Methods', Discussion paper prepared for the workshop in Hamburg, 15-16 March 2010.

Group of Advisers on the Ethical Implications of Biotechnology (GAEIB) to the European Commission (1997), *Ethical Aspects of Cloning Techniques*, 28 May 1997, http://ec.europa.eu/european_group_ethics/docs/opinion9_en.pdf.

Joined Cases C-371/04 and 318/04, *European Parliament v Council of the European Union and Commission of the European Communities* [2006] ECR I-04721.

Haberle, Peter (2003), *El Estado Constitucional*. México: Universidad Nacional Autónoma de México, Instituto de Investigaciones Jurídicas.

Habermas, Jurgen (1996), *Between Facts and Norms, Contributions to a Discourse Theory of Law and Democracy*, Cambridge: The MIT Press.

Habermas, Jurgen (1986), *Law and Morality*, The Tanner Lectures. Cambridge: Harvard University.

Harris John (1998), 'Cloning and Human Dignity', *Cambridge Quarterly of Healthcare Ethics*, No. 7, pp.163-167.

Hert, Paul de (2005a), 'Balancing security and liberty within the European human rights framework. A critical reading of the Court's case law in the light of surveillance and criminal law enforcement strategies after 9/11', *Utrecht Law Review*, Vol. 1, Issue 1, http://.cfm?abstract_id=991586.

Hert, Paul de (2005b), 'Biometrics: legal issues and implications', Background paper for the Institute of Prospective Technological Studies, DG-JRC, Sevilla, European Commission, http://cybersecurity.jrc.ec.europa.eu/docs/LIBE%20Biometrics%20March%2005/LegalImplications_Paul_de_Hert.pdf.

Hobbes, Thomas (2008), *The Leviathan*, London: Penguin Books (First published: 1651).

House of Lords, EU Select Committee (2007-08), *The Treaty of Lisbon: An Impact Assessment*, 10th Report, HL62-I.

Hustinx, Peter (2009), 'Data Protection in the Light of the Lisbon Treaty and the Consequences for Present Regulations' 11th Conference on Data Protection and Data Security, Berlin, http://www.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/EDPS/Publications/Speeches/2009/09-06-08_Berlin_DP_Lisbon_Treaty_EN.pdf.

IPTS - Institute for Prospective Technological Studies (2005), 'Biometrics at the Frontiers: Assessing the Impact on Society', Joint Research Centre, European Commission , http://ec.europa.eu/justice_home/doc_centre/fretravel/doc/biometrics_eur21585_en.pdf.

Kotschy, Waltraut (2008), 'Processing of personal data relating to health in electronic health records', *Dataprotectionreview.eu*, Issue 5, February 2008, <http://www.dataprotectionreview.eu/>.

Liberatore, Angela (2007), 'Balancing Security and Democracy, and the Role of Expertise: Biometrics Politics in the European Union', *European Journal on Criminal Policy and Research*, No. 13, pp. 109-137.

Marche, Régis (2008), 'Conflits de valeurs entre la recherche et la société', in *Quel droit pour la recherche ?*, Isabelle de Lamberterie, Étienne Vergès (dir.), Paris: LexisNexis, pp. 33-41.

Marx, Gary T. (1988), 'La société de sécurité maximale', *Déviance et Société*, Vol. 12, No. 2, pp. 147-166.

Marx, Gary T. (2008), 'Vigilância soft – o crescimento da voluntariedade obrigatória na recolha de dados pessoais. ó amigo, empresta-me uma amostra de DNA?'. In C. Fróis (ed.), *A Sociedade Vigilante*, Lisbon: Imprensa da Ciências Sociais, pp. 87-109.

Meisch, Simon; Potthast, Thomas (2010), 'Values in Society', Synthesis meeting Hamburg, March 2010 Working Paper.

Morin, Edgar (2004), 'L'éthique de la complexité et le problème des valeurs au XXI^e siècle', in *Où Vont les Valeurs ?*, Jerome Bind (dir.), Paris : Éditions Unesco/Albin Michel.

Munster, Rens van (2005), 'The EU and the Management of Immigration Risk in the Area of Freedom, Security and Justice', *Political Science Publications*, n° 12, http://www.sdu.dk/~media/Files/Om_SDU/Institutter/Statskundskab/Skriftserie/05Rens12%20pdf.aspx.

Opinion of Advocate General Trstenjak on the Case C-137/05, United Kingdom of Great Britain and Northern Ireland v Council of the European Union [2008] ECR I- 02245.

Raz, Joseph (1994), *Ethics in the Public Domain, Essays in the Morality of Law and Politics*, Clarendon Paperbacks, Oxford University Press, Oxford, New York.

Robinson, Neil, et al. (2009), *Review of the European Data Protection Directive*, Rand Europe.

Schachter, Oscar (1983), 'Human Dignity as a Normative Concept', *American Journal of International Law*, Vol. 77, No. 4, pp. 848-854.

Scirocco, Alfonso (2008), 'The Lisbon Treaty and the Protection of Personal Data in the European Union', *DataProtectionReview.eu*, Issue 5, February 2008, <http://www.dataprotectionreview.eu/>

Terré, Dominique (2007), *Les Questions Morales du Droit*. Paris: PUF.

Treaty on the Functioning of the European Union, 2009.

Tsakyrakis, Stavros (2008), 'Proportionality: An assault on Human Rights?', Jean Monnet Working Paper 09/08, <<http://centers.law.nyu.edu/jeanmonnet/papers/08/080901.pdf>>.

Unesco (2005) *Report on The Precautionary Principle*, Paris: Unesco.

UNESCO (1997), Universal Declaration on the Human Genome and Human Rights, adopted on 11 November 1997 by the General Conference of UNESCO, *Records of the General Conference*, 29th Session Resolutions, 21 October – 12 November, Volume I, Paris: UNESCO, pp. 41-46. <http://unesdoc.unesco.org/images/0011/001102/110220e.pdf#page=47>.

United Nations General Assembly, Declaration on Human Cloning, Resolution 59/280, 8 March 2005.

Von Bogdandy, Armin (2000), 'The European Union as a Human Rights Organization? Human Rights and the core of the European Union', *Common Market Law Review* 37, pp. 1307-1338.

Williams, Andrew T. (2009), 'Taking Values Seriously: Towards a Philosophy of EU Law', *Oxford Journal of Legal Studies*, Vol. 29, No. 3, pp. 549-577.

Wynne, Brian et al. (2007), *Taking Knowledge Society Seriously*, Brussels: European Commission.

Zagrebelsky, Gustavo (2002), 'Diritto per: valori, principi o regole? (a proposito della dottrina dei principi di Ronald Dworkin)', *Quaderni fiorentini per la storia del pensiero giuridico moderno*, Vol. 31, pp. 865-897.

Case-law

Case C-165/08, Commission of the European Communities v Republic of Poland, [2009] ECR I-00000.

S. and Marper v. the United Kingdom [GC], nos. 30562/04 and 30566/04, ECHR 2008.

Case C-137/05, United Kingdom of Great Britain and Northern Ireland v Council of the European Union [2007] ECR I-11593.

Case T-326/99, Nancy Fern Olivieri v Commission of the European Communities and European Agency for the Evaluation of Medicines (EMA), Rec.2003, p.II-6053.

Case C-377/98, Kingdom of the Netherlands v European Parliament and Council of the European Union [2001] ECR I-07079.

Opinion of Mr Advocate General Jacobs delivered on 14 June 2001, Kingdom of the Netherlands v European Parliament and Council of the European Union, Case C-377/98 [2001] ECR I-07079.

Selected links

- Art.29 Data Protection Working Party
http://ec.europa.eu/justice_home/fsj/privacy/workinggroup/index_en.htm
- Centre for Science, Society and Citizenship <http://www.cssc.eu/index.php>
- Comité Consultatif National d'Ethique pour les Sciences de la Vie et de la Santé
<http://www.ccne-ethique.fr/leccne.php>
- Council of Europe http://www.coe.int/t/e/legal_affairs/legal_co-operation/Data_protection/
- Electronic Privacy Information Centre (EPIC) <http://epic.org/>
- European Biometrics Forum <http://www.eubiometricsforum.com/>
- European Parliament Committee on Civil Liberties, Justice and Home Affairs
http://www.europarl.europa.eu/committees/libe_home_en.htm
- Human Genetics Commission, UK <http://www.hgc.gov.uk/Client/index.asp?ContentId=1>

- International Bioethics Committee (IBC) http://portal.unesco.org/shs/en/ev.php-URL_ID=1879&URL_DO=DO_TOPIC&URL_SECTION=201.html
- Intergovernmental Bioethics Committee (IGBC) http://portal.unesco.org/shs/en/ev.php-URL_ID=1878&URL_DO=DO_TOPIC&URL_SECTION=201.html
- Nuffield Council on Bioethics <http://www.nuffieldbioethics.org/>
- Privacy International <http://www.privacyinternational.org/>
- Science and Technology Options Assessment http://www.europarl.europa.eu/stoa/default_en.htm
- Statewatch <http://www.statewatch.org/>
- World Stem Cell Map <http://www.mbbnet.umn.edu/scmap.html>

LIST OF EUROPEAN LEGAL INSTRUMENTS 2000 – 2010

The following list comprises a selection of ethically-related EU policy and legal documents regarding science and technology, organised by major policy areas. A word-search of the terms ‘ethics’ and ‘ethical’ in EU law and regulation related to science and technology, carried out for the purposes of this report, resulted in the identification of around 80 legal instruments adopted in the time period going from 1975 to 1999, and of around 100 legal instruments from 2000 to 2010 (the total number of S&T legal instruments also increased in the second period).³³

SECURITY, DATA PROTECTION AND BIOMETRICS

Communication from the Commission to the European Parliament and the Council – An area of freedom, security and justice serving the citizen, COM (2009) 262 final.

Commission Recommendation of 12 May 2009 on the implementation of privacy and data protection principles in applications supported by radio-frequency identification, 2009/387/EC.

Communication from the Commission to the European Parliament and the Council on Promoting Data Protection by Privacy Enhancing Technologies (PETs), COM(2007) 228 final.

Council Regulation (EC) N° 2252/2004 of 13 December 2004 on standards for security features and biometrics in passports and travel documents issued by Member States.

Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, ‘Security Research: The Next Steps’, COM(2004) 590 final.

Commission Communication on the implementation of the Preparatory Action on the enhancement of the European industrial potential in the field of Security research, Towards a programme to advance European security through Research and Technology, COM(2004) 72 final.

Communication from the Commission to the Council and the European Parliament towards integrated management of the external borders of the Member States of the European Union, COM(2002) 233 final.

Opinion of the Economic and Social Committee on the ‘Commission Working Document — The relationship between safeguarding internal security and complying with international protection obligations and instruments, COM(2001) 743 final.

Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

HUMAN CLONING AND CELL RESEARCH

³³ ‘Ethical related questions’ arise frequently in written questions submitted by members of the European Parliament to the Commission.

Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

Report from the Commission to the Council and the European Parliament – Development and implications of patent law in the field of biotechnology and genetic engineering, COM(2005) 312 final.

Report from the Commission to the European Parliament, the Council, the Committee of the Regions and the European Economic and Social Committee – Life Sciences and Biotechnology – a Strategy for Europe, third progress report and future orientations, COM(2005) 286 final.

Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee, Life Sciences and Biotechnology – A Strategy for Europe, second progress report and future orientations, COM(2004)250 final.

European Commission Staff Working Paper – Report on human embryonic stem cell research, SEC (2003) 441.

Common position (EC) No 50/2003 adopted by the Council on 22 July 2003 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, 2003/C 240 E/02.

Communication from the Commission to the European Parliament, to the Council and to the European Economic and Social Committee ‘Life Sciences and Biotechnology –A strategy for Europe, progress report and future orientations’, COM(2003) 96 final.

Opinion of the European Economic and Social Committee on the ‘Communication from the Commission to the European Parliament, to the Council and to the European Economic and Social Committee on Life Sciences and Biotechnology — A strategy for Europe Progress report and future orientations’, COM(2003) 96 final.

Opinion of the Economic and Social Committee on the ‘Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions: Life sciences and biotechnology— A Strategy for Europe’, 2003/C 61/04.

Opinion of the European Economic and Social Committee on the ‘Proposal for a Directive of the European Parliament and of the Council setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells, COM(2002) 319 final.

Proposal for a Directive of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells, COM(2002) 319 final.

Opinion of the Economic and Social Committee on the ‘Communication from the Commission — Towards a strategic vision of life sciences and biotechnology: consultation document’, 2002/C 94/07.

Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions, ‘Life sciences and biotechnology – A Strategy for Europe’, COM(2002) 27 final.

European Parliament resolution on human cloning, 7 September 2000.

GMO AND NOVEL FOODS

Position (EU) No 6/2010 of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001.

Green Paper on agricultural product quality: product standards, farming requirements and quality schemes, COM(2008) 641 final.

Commission staff working document - Accompanying document to the second report from the Commission to the Council and the European Parliament on the experience of member states with GMOs placed on the market under Directive 2001/18/EC, COM(2007) 81 final.

Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX [common procedure], COM(2007) 872 final.

Commission staff working document - Annex to the Communication from the Commission to the Council and the European Parliament - Report on the implementation of national measures on the coexistence of genetically modified crops with conventional and organic farming, COM(2006) 104.

Commission Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.

Commission Regulation (EC) No 65/2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms.

Regulation (EC) No 1946/2003 on transboundary movements of genetically modified organisms.

Commission Recommendation No 2003/556/EC on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming.

Regulation (EC) No 1830/2003 on traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

Regulation (EC) No 1829/2003 on genetically modified food and feed.

Opinion of the Committee of the Regions on the Proposal for a Regulation of the European Parliament and of the Council on the transboundary movement of genetically modified organisms OJ 278, 14/11/2002 P. 0031 – 0035.

Opinion of the Committee of the Regions on the Proposal for a Regulation of the European Parliament and of the Council on genetically modified food and feed OJ 278, 14/11/2002 P. 0031 – 0035.

Opinion of the Committee of the Regions on the Proposal for a Regulation of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, OJ 278, 14/11/2002, P. 0031 – 0035.

Regulation (EC) No 178/2002 laying down the general principles and requirements of food law.

Report from the Commission to the European Parliament and the Council – Development and implications of patent law in the field of biotechnology and genetic engineering, COM(2002) 545 final.

Opinion of the Economic and Social Committee on the ‘Proposal for a Regulation of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC’, COM(2001) 182 final.

Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

White Paper on Food Safety, COM (1999) 719 final.

Council Directive 98/81/EC amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS (REACH)

Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 142 , 31/05/2008 P. 0001 – 0739.

Commission Staff Working Document – Accompanying document to the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, Regulatory Aspects of Nanomaterials, Summary of legislation in relation to health, safety and environment aspects of nanomaterials, regulatory research needs and related measures, COM(2008) 366 final.

Common Position (EC) No 17/2006 adopted by the Council on 27 June 2006 with a view to adopting Regulation (EC) No .../2006 of the European Parliament and of the Council of... concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC of the European Parliament and of the Council and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, 2006/C 276 E/01.

Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (Reach), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) on Persistent Organic Pollutants, COM/2003/0644 final.

White Paper Strategy for a future Chemicals Policy, COM(2001) 88 final.

NANOSCIENCES AND NANOTECHNOLOGIES

Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee, ‘Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009. Second Implementation Report 2007-2009’, COM(2009) 607 final.

Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, 'Regulatory aspects of nanomaterials', COM(2008) 366 final.

Opinion of the European Economic and Social Committee on the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee – Regulatory aspects of nanomaterials, COM(2008) 366 final.

Commission Recommendation of 7 February 2008 on a code of conduct for responsible nanosciences and nanotechnologies research, 2008/345/EC.

Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee, 'Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007', COM(2007) 505 final.

Opinion of the European Economic and Social Committee on the Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee — Nanosciences and nanotechnologies: An action plan for Europe 2005-2009, 2006/C 185/01.

European Parliament resolution on nanosciences and nanotechnologies: an action plan for Europe 2005-2009 (2006/2004(INI)), 15.12.2006, P6_TA(2006)0392.

Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee, Nanosciences and nanotechnologies: An action plan for Europe 2005-2009, COM(2005) 243 final.

Communication from the Commission, Towards a European strategy for nanotechnology, COM(2004) 338 final.

Opinion of the European Economic and Social Committee on the 'Communication from the Commission: Towards a European strategy for nanotechnology', COM(2004) 338 final.

7TH FRAMEWORK PROGRAMME

Council Decision 2006/975/EC of 19 December 2006 concerning the specific programme to be carried out by means of direct actions by the Joint Research Centre under the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 to 2013), OJ L 400, 30.12.2006.

Communication from the Commission to the European Parliament concerning the common position of the Council on the adoption of a Decision of the European Parliament and of the Council concerning the 7th Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013), COM(2006) 548 final.

OTHER

Conclusions of the Council on the definition of a 2020 vision for the European research area, 2009/C 25/01.

Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions “Preparing for our future: Developing a common strategy for key enabling technologies in the EU”, COM(2009) 512 final.

Communication from the Commission to the European Parliament and the Council – Building a sustainable future for aquaculture A new impetus for the Strategy for the Sustainable Development of European Aquaculture, COM(2009) 162 final.

Communication from the Commission to the Council and the European Parliament ‘The European Research Council - Meeting the challenge of world class excellence COM(2009) 552 final.

European Parliament resolution of 22 May 2008 on a new animal health strategy for the European Union 2007-2013, P6_TA(2008)0235 (2009/C 279 E/20).

Opinion of the Committee of the Regions on ‘Mid-term review of the Strategy on Life Sciences and Biotechnology’, 2008/C 105/02.

Communication from the Commission – A Community framework on the application of patients' rights in cross-border healthcare, COM(2008) 415 final.

Opinion of the European Economic and Social Committee on the Communication from the Commission to the Council and the European Parliament: A strategic European framework for international science and technology cooperation, COM(2008) 588 final.

Opinion of the European Economic and Social Committee on the ‘Mid-term assessment of implementing the EC Biodiversity Action Plan’, COM(2008) 864 final.

Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004.

White Paper ‘The European Research Area: New Perspectives’, COM(2007) 161 final.

Opinion of the European Economic and Social Committee on Unlocking and strengthening Europe's potential for research, development and innovation, 2006/C 325/05.

Opinion of the European Economic and Social Committee on the Proposal for a Regulation of the European Parliament and of the Council on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004, COM(2005) 567 final.

Commission Recommendation of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers, 2005/251/EC.

Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products.

Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, ‘Towards a Global Partnership in the Information Society: The Contribution of the European Union to the Second Phase of the World Summit on the Information Society (WSIS)’, COM(2005) 234 final.

Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Opinion of the European Economic and Social Committee on the Communication from the Commission to the Council and the European Parliament — Stimulating technologies for sustainable development: an environmental technologies action plan for European Union, COM(2004) 38 final.

Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use.

Commission Regulation (EC) No 1085/2003 the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93.

Commission Regulation (EC) No 1084/2003 on the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State.

Opinion of the European Economic and Social Committee on the ‘Proposal for a Council Decision amending Decision 2002/834/EC on the specific programme for research, technological development and demonstration: ‘Integrating and strengthening the European research area (2002-2006)’, COM(2003) 390 final.

Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use.

Council Decision 2002/835/EC adopting a specific programme for research, technological development and demonstration: ‘structuring the European Research Area’ (2002–2006).

Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions – Science and Society Action plan, COM(2001) 714 final.

Opinion of the Economic and Social Committee on ‘the Commission Staff Working SEC(2000) 1973 “Science, society and the citizen in Europe”’, 2001/C 221/25.

Opinion of the Economic and Social Committee on ‘Use of the precautionary principle’, 2000/C 268/04.

Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work.

Charter of Fundamental Rights of the European Union

1. Human dignity and human life (Articles 1 and 2)

These principles/rights constitute the core of human rights, and show up frequently in the legislation addressing scientific research and technological innovation. Alongside with the right to the integrity of the person, these are the most quoted principles in European legal instruments related with science and technology.

The preparatory documents of the Charter state explicitly that human dignity is ‘the bedrock of all fundamental rights’.³⁴

2. Right to the integrity of the person (Article 3)

Especially present in the legislation, the right to the integrity of the person is also guaranteed in connection with scientific and technological activities, specifically regulation of the life sciences and technologies. Paragraph 2, addressing medicine and biology states the respect for ‘the free and informed consent of the person concerned, according to the procedures laid down by law; the prohibition of eugenic practices, in particular those aiming at the selection of persons; the prohibition on making the human body and its parts as such a source of financial gain; the prohibition of the reproductive cloning of human beings’. The free and informed consent of the donor and recipient in the context of medicine and biology was restated in the judgment of 9 October 2001 in Case C-377/98 Netherlands v European Parliament and Council. These principles were already present in the Convention on Human Rights and Biomedicine.

4. Respect for private life and protection of personal data (Articles 7 and 8)

Article 7 draws its inspiration from Article 8 of the European Convention of Human Rights, substituting the word ‘correspondence’ for ‘communications’ to account for the developments in means of communication.³⁵ Article 8 on personal data protection finds its roots in the 1981 Council of Europe’s Convention on the Protection of Individuals with regard to Automatic Processing of Personal Data.

³⁴ Charte 4147/00, Convent 11, p. 5.

³⁵ Charte 4149/00, Convent 13, p. 13.

In the legislation regulating science and technology, the rights to privacy and to personal data protection tend to be referred together. However, the Charter chose to split them, allowing for a specific reference to data protection.³⁶

Before the entering into force of the Charter, the protection of personal data was already in place in the European Union, through Directive 95/46/EC and Regulation N° (EC) 2252/2004 applicable to EU institutions.

5. Freedom of information (Article 11)

Article 11 states that ‘this right shall include freedom to (...) receive and impart information and ideas’. It is the only principle in the Charter that may encompass a right to access to information and public participation in decision-making processes, developed earlier in the Convention of Aarhus of 1998 regarding access to information, public participation and access to justice in the field of the environment.

6. Freedom of sciences (Article 13)

This principle, related with the right to freedom of thought and expression, declares the ‘freedom of sciences’ understood as freedom of research in a broad way: ‘scientific research shall be free of constraint’. Explicitly the Charter provides for just one restriction to this freedom, with respect to research involving humans. But, necessarily, this principle must be balanced against other principles and rights, being ‘subject as all other rights to the respect of human dignity’.³⁷ In early drafts of the Charter, this principle was included in the provision on freedom of expression.³⁸

7. Freedom to conduct a business and right to property (Articles 16 and 17)

The freedom to conduct a business recognises the freedom to practice a commercial or economic activity in the European Union, but it can be understood in a broader sense as protecting the market, namely the internal market, and free competition. According to the explanations of the preparatory works of the Convention, it is based on ECJ’s case law recognising freedom to exercise economic or commercial activities, freedom to contract and free competition.³⁹

The right to property includes intellectual property, a growingly relevant matter in the European Union, and especially in the field of science and technology.

8. Non-discrimination (Article 21)

³⁶ Charte 4137/00, Convent 8, p. 5

³⁷ Charte 4149/00, Convent 13, p. 16.

³⁸ ‘Article 15: Freedom of expression, n° 2: Art, science and research shall be free of constraint.’ CHARTE 4149/00, Convent 13, p. 15. In the draft version Charte 4470/00, Convent 47, p. 6 the article was already independent.

³⁹ Charte 4423/00, Convent 46, p. 14.

In the Charter of Fundamental Rights this principle refers to a broad number of non discrimination grounds. Discrimination based on genetic features draws from the Convention on Human Rights and Biomedicine (Article 11).

9. Cultural and religious diversity (Article 22)

Cultural and religious diversity are relevant principles with ethical implications. In the legislation analysed there are considerable references to not giving raise to ‘ethical or religious concerns’. Human cloning is an example of a scientific development seen in a different fashion among religions. Judaism and Islamism accept to some extent research with human tissues, whereas the Catholic Church strongly opposes it.

10. The rights of the child, of the elderly and integration of persons with disabilities (Articles 24, 25 and 26)

Some particular references are made throughout the legislation to the rights of particular groups, especially to minors and persons with disabilities, assuring these groups special protection.

11. Health care (Article 35)

The Charter affirms that ‘a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities’.

12. Environmental protection (Article 37)

The Convention discussed if environmental protection should be considered as a right or as an obligation and, in this connection, raised the distinction between individual and collective rights.⁴⁰

13. Consumer protection (Article 38)

Like environmental protection, consumer protection is a principle often mentioned in European regulatory instruments. In the preparatory work for the Charter the proposal was put forward to include a reference to the precautionary principle in this article, that was eventually rejected but.⁴¹

⁴⁰ Record of the second meeting of the Convention to draw up a draft Charter of Fundamental Rights of the European Union, CHARTE 4134/00, Convent 6, p. 3.

⁴¹ CHARTE 4383/00, Convent 41, p. 22.

World Cloning Legislature

	ESC*	Ther.	Ban**		ESC	Ther.	Ban**
Argentina	×		×	Latvia	×		×
Australia	×		×	Lithuania			×
Austria			×	Netherlands	×		×
Belgium	×	×		New Zealand	×	×	
Brazil	×		×	Norway			×
Canada	×		×	Panama	×		×
Chile	×		×	Peru	×		×
China	×	×		Poland			×
Columbia	×	×		Portugal	×		×
Costa Rica			×	Russian Federation	×		×
Czech Republic	×		×	Singapore	×	×	
Denmark	×		×	Slovakia			×
Ecuador			×	Slovenia	×		×
Egypt	×		×	South Africa	×		×
Estonia	×		×	South Korea	×	×	
Finland	×	×		Spain	×		×
France	×		×	Sweden	×	×	
Georgia	×		×	Switzerland	×		×
Germany	×		×	Taiwan	×		×
Greece	×		×	Thailand	×	×	
Hungary	×			Trinidad & Tobago			×
Iceland	×		×	Tunisia	×		×
India	×			Turkey	×	×	
Iran	×			Ukraine	×		
Ireland			×	United Kingdom	×	×	
Israel	×	×		United States	×	×	
Italy			×	Uruguay	×		
Japan	×	×		Vietnam	×		×

Table 1

*Some prohibit the derivation of embryonic stem cells, but do not specifically prohibit the research using existing lines.

**Ban refers to countries which banned human cloning (both reproductive and therapeutic).

Overview of world human cloning policies (as in 2007):

'ESC' – Countries that don't prohibit research using existing stem cell lines

'Ther.' – Countries that don't prohibit therapeutic cloning

'Ban' – Countries that have banned human cloning altogether

UNESCO (2004), National Legislation concerning Reproductive Human Cloning and Therapeutic Cloning, <http://unesdoc.unesco.org/images/0013/001342/134277e.pdf>

<http://cnx.org/content/m14834/latest/> (August 2007)

European values, fundamental rights and EU law and politics on biometrics

Maria Eduarda Gonçalves, Maria Inês Gameiro

Fifth Pan-European Conference on European Politics
Universidade do Porto, 25 June 2010

DINÂMIA – CET

Center for Socioeconomic and Territorial Studies

Project:

***Value Isobars – The Landscape and Isobars
of European Values in Relation to Science
and New Technology
(EU 7th Framework Programme)***

www.value-isobars.eu

Contents

1. Introduction
2. Values, legal principles and rights
3. Values in European law addressing science and technology: the case of biometrics
4. Final remarks

Central questions

Which values are being summoned by European law and regulation shaping the development and deployment of science and technology?

How are relevant principles and rights being tackled by EU regulation of biometrics?

What does that tell us about the ‘value system’ embedded in European law on science and technology (S&T) more generally?

Ideas underlying the research

- **The Charter of Fundamental Rights of the EU constitutes, alongside other legal instruments, the main legally binding framework of value-based European principles and rights**
- **Yet, is the new EU discourse focused on human values and the rights of the person shaping the legal and regulatory frameworks for sciences and technologies?**
- **Biometrics provide an interesting study case for such analysis.**

BIOMETRICS



Biometric technology has become:

- one of the central pieces of national and international security and immigration policies in Europe following the ‘9/11’ when security measures became more tightened worldwide approaching the idea of a ‘maximum security society’ (Marx 1988)**
- increasingly important economically as it is more and more employed to control access of workers, students, and other categories of people in various organisations**

The values interfered with by biometrics can be divided in two sets:

- Security and related rights
- Liberty, privacy, intimacy, human dignity and related rights (namely, data protection)

The classic and broader confrontation between security and democracy also comes up in this connection.

The right to conduct a business and the freedom of research also play a part in the biometrics' 'rights balance' to the extent that development and economic investment in biometric technologies are recognised as legitimate rights.

EU legal framework on biometrics

Article 6 of the Charter addresses *liberty and security* as part of an *unique right*.

However, this 'right to liberty and security' raises a number of questions:

- **Why have liberty and security been treated in an integrated manner in the Charter?**
- **Should they be regarded as the two faces of the same coin or rather as conflicting principles or rights?**

- Decision N° 1982/2006/EC approving the 7th Framework Programme for Research and Development follows the same direction stating that ‘security in Europe is a *precondition of prosperity and freedom*’.

Security technologies, including biometrics, are a priority area for R&D under this programme.

- Regulation N° 2252/2004 - Biometrics in passports and travel documents

Basically a technical normative text, rather than a value or rights-oriented one.

In reality, the introduction of biometrics as such was not questioned from the fundamental human rights' angle.

-The European legislator has limited its consideration to biometrical data protection, disregarding the implications of the employment of biometrics on the individuals' intimacy component of privacy and on the exercise of freedom and democracy more generally.

Applying the data protection regime (Directive 95/46/EC) to biometrical data implies the presumption of the legitimacy of biometrics.

- n **The merging of liberty and security into one single right may have been a political stratagem to render EU security policy more acceptable to the European public.**
- n **‘The driving force has of course been *entirely political* and aimed at demonstrating some sort of response to terrorism and national security, while simultaneously introducing vastly increased powers of law enforcement activity.’ (IPTS 2005, p. 20).**

- n **However, conceiving security and liberty as merged into one single principle or right undervalues these rights' conflict.**

‘If we continue blindly along this path, where will it take us in 10, 20 and 30 years from a societal perspective?’ (IPTS 2005)

- n **The Art. 29 Data Protection Working Party, acknowledging the hypersensitive nature of biometrical data, considers that these data should only be used in a subsidiary way, that is, whenever ‘less intrusive material’ does not allow the same effect. But no specific regime has been adopted for biometrical data up to this day.**

In sum

Biometrics has been framed by the EU primarily in light of security values and commercial interests in detriment of the consideration of its implications for the exercise of freedom and democracy

Limitations of the procedures that led to adoption of biometrics have also been recognised:

‘It is time also to bring citizens squarely into the debate. Not by carefully manipulated opinion polls, but by honest and open public discussion. (...). The dialogue to date has been heavily influenced by commercial interest and political aspirations. There has been remarkably little genuine consultation with citizens on a matter which will have a significant impact upon society.’ (IPTS 2005, p. 21).

Concluding,

Up to now expectations opened up by the Charter on Fundamental Rights for a renewed and stronger responsibility of EU institutions to promote a balanced, value-based regulation of biometrics end up somewhat frustrated.

How may this state of affairs be changed?



Thank you

European values, fundamental rights and EU law and politics on biometrics*

Maria Eduarda Gonçalves, Maria Inês Gameiro

DINAMIA, ISCTE- IUL

1. Introduction

Article 2 of the Treaty on European Union consolidated by the Treaty of Lisbon affirms that ‘The Union is founded on the **values** of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights, including the rights of persons belonging to minorities.’ Following up from this general declaration, Article 3 specifies EU’s fundamental objectives: first, an area of freedom, security and justice in which the free movement of persons is matched with appropriate border controls (nº. 2); second, an internal market based on balanced economic growth, a competitive social market economy and a high level of protection and improvement of the quality of the environment. An additional objective of the internal market is to ‘*promote scientific and technological advance*’ (nº. 3).

The explicit reference to *values* in the Treaty stands for a novelty of the Lisbon Treaty. However, reference to *liberty, democracy, respect for human rights and fundamental freedoms* is not an originality of the Lisbon Treaty. The Treaty of European Union (Maastricht, 1992) embraced them under the reference to *principles* (Article 6). Adding the epithet of values (as guiding ideals, one might say) to these principles may be seen as a symbolic reinforcement of what already represented, with Maastricht, a breakthrough from the original Treaty of Rome establishing the European Economic Community (EEC) (1957). As a matter of fact, the objective of the EEC was primarily economic, i.e., the establishment of ‘a common market and an economic and monetary union’ (Article 1) and of common policies in the fields of agriculture, transports, and external trade (Article 3). In that context prevalence was assigned to *basic economic freedoms*, namely, the free circulation of workers and capital, free trade and the free establishment of enterprises in EEC’s territory.

* This paper is based on work undertaken as part of the research project ‘The Landscape and Isobars of European Values in Relation to Science and New Technology (Value Isobars)’, 7th Framework Programme on R&D, European Union.

Priority was given for many decades to market-based objectives as shown, in particular, by the primacy of market ‘freedoms’ in the European Court of Justice’s case-law.^{1 2}

Even after the entering into force of the Treaty of the European Union, in 1992, the scope of civil and political rights in the Treaty remained confined to *European citizenship* involving the rights to freedom to move and to reside within the territories of the member states (Article 2) and to participate in municipal elections in their member state of residence (Article 18). Only lately, following the failed attempt to adopt a European Constitution and the subsequent adoption of the Treaty of Lisbon (2009) the way was paved for a true focus of EU political and legal discourse on **human values**. It is in this context that the Charter of Fundamental Rights of the EU was brought into life with binding force, even if not incorporated in the Treaty of Lisbon (Article 6 TEU).

No doubt, the Charter and the Treaty of Lisbon now offer a prime setting for the expression of the most prized *values* of Europe, meaning of course the European Union. Yet, while the adoption of the Charter with binding force should direct EU institutions in the design of law and policy, the question remains of how such effect will work in practice.

A domain falling under the EU’s scope of responsibility in which respect for the Charter’s values and principles is in this day and age especially critical is surely *science and technology*. *Scientific and technological advance*, as already pointed out, was proclaimed by the TEU as a key goal of the internal market. In turn, the Charter of Fundamental Rights states the EU intent ‘to strengthen the protection of fundamental rights in the light of changes in society, social progress and *scientific and technological developments* by making those rights more visible in a Charter.’ New scientific and technological advances such as inter alia genetically modified organisms, nanotechnologies, animal and human cloning, or security technologies have a bearing on moral and ethical values perceived by European societies as fundamental, including human dignity and integrity, as well as values typical of the contemporary post-industrial society such as environmental protection and consumer safety. All these values find expression in the Charter of Fundamental Rights in the form of *fundamental principles or rights*. It should also be recalled that, notwithstanding their

¹ See Curzon, 2009, p. 110 and 116, acknowledging the tendency of the ECJ to ‘subordinate fundamental rights protection to the protection of fundamental economic freedoms’, possibly related to the ‘unbreakable bond between the European Court of Justice and the founding treaties which created it’. According to this author, even as it developed, timidly and slowly, protection of fundamental rights by the ECJ continued to be perceived as an exception to the general rule of market’s fundamental freedoms (Curzon 2009, p. 122).

² In the EU context, human rights are most often referred to as ‘fundamental rights.’ No major conceptual difference is involved, and the terms will be used interchangeably in this report. The distinction between fundamental (human) rights (not listed in the Treaties) and fundamental (economic) freedoms (listed in the Treaties) is relevant, however. Some consider the economic freedoms to be human rights, but that is not the generally accepted view, see Bogdandy 2000, p. 1326.

equivalent status as principles of law and/or human rights, several of such principles and rights are amenable to collide with each other in theory as well as in concrete instances. Indeed, conflict or clash of rights is a familiar notion to the law, as is the proportionality principle that seeks to address this conflict (Tsakyrakis 2008).

It seems, therefore, reasonable to ask how the new EU rhetoric focusing on human values and rights might shape the legal and regulatory frameworks for scientific research and technological applications by looking at how the underlying balances of conflicting values, principles and rights have been addressed in the recent past.

The Charter has by now been regarded as an effort to make human rights ‘determine’ rather than simply ‘limit’ an EU legal system predominantly designed to guarantee market freedoms, implying a demand to the legislator and judiciary to ‘tilting the balance between regulatory policies and individual freedoms in favour of the latter’ (von Bodgandy 2000, p. 1321). It has also been argued, a process mirroring the construction of the internal market may be in the making for fundamental human rights: from ‘negative’ rights and freedoms implying the prohibition or limitation of certain acts to ‘positive’ rights and freedoms, in other words, ‘a comprehensive, coherent, balanced and forward-looking *human rights policy*’ (Alston and Weiler 1999, p. 8). Is this aim mere wishful thinking? To what extent is it being pursued, one might ask?

Against this backdrop, this paper aims to *critically appraise how human or social values rendered explicit through the Charter’s principles and rights are being balanced against the promotion of scientific and technological advance*. This appraisal will be based on the current EU legal framework for *biometrics*, a new security technology whose development is being supported under the EU Research and Development (R&D) policy, and is employed mainly for individual and social surveillance purposes. Biometrics elicits complex ethical and legal challenges that have been addressed by European law lately. The selection of this technology for the purposes of the present analysis lay on two main interrelated criteria: its controversial or contested nature that we take as an indicator of social sensitivity or anxiety in that regard; and the extent to which it raises moral or ethical dilemma around basic values such as human dignity, individual autonomy, liberty or privacy. Our assumption is that the present state of affairs in the EU, where the design to promote scientific and technological progress goes alongside growing public fears about both ethical and social issues and potential adverse impacts of science and technology, underlines the need for a value-oriented framework for scientific and technological development and a value-based governance of science and technology.

This paper will start by clarifying the key relevant concepts, values, principles and rights. Legal principles and human rights will provide the main entry points for our *review of values in EU S&T law and regulation* in respect of biometrics, to be ascertained from a reading of the EU Charter on Fundamental Rights. This preliminary review aims to identify the values at issue, and how they relate or collide with each other: for example, Article 3 (Right to the integrity of human being) and the specific restrictions applicable to the fields of medicine and biology contained in the same article (e.g., the free and informed consent of the person concerned or the prohibition on making the human body and its parts as such a source of financial gain) may interfere with the freedom of the sciences guaranteed by Article 13; similarly, Article 8 on the right to protection of personal data may conflict with Article 16 on the right to conduct a business (or right to free enterprise). This right can be regarded as the legal background for technological and industrial innovation. The ways in which EU law and regulation are tackling these principles and rights, in theory and in practice, will be discussed in the light of the selected case study.

2. Values, legal principles and rights

Values understood as standards of morality or justice and/or ends or ideals to be pursued enter the law through legal principles and legal rights. Many norms are or can be justified by values or high substantial principles such as justice or human rights.

Values, it has been suggested, may be approached through two consecutive steps: first, a reflection about values and, second, the definition of norms referring to those values and leading to rules, including legal rules (Mache 2006, p.34). Although values, principles and rules have been for a long time immersed in ‘confusion and controversy’ (Alexy 2010, p. 45), broadly speaking, law is essentially shaped by values: on a more general and abstract level, by law’s intrinsic values of justice, equality and security, and on a more applied level by those that are codified through the choices of the legislator in each domain of policy or regulation. The former tend to be universal while the latter are evolving and changing, framed by a society undergoing permanent processes of adjustment, nowadays, in particular, to a ‘new relationship between the law, science and technology’ (Morin 2004, p. 94).

Values generally lead to principles translating into rights and from these to rules and regulatory instruments in a ‘series of interlocking definitions and distinctions’ (Dworkin 1977, p. 18). Such a ‘legal cascade’ thus flows from normative principles to ordinary law and case-law, as well as to soft-law instruments such as codes of conduct. Attention should be drawn to the fact that there is no rigid legal order hierarchy any longer. Different layers of

principles and norms interrelate and influence each other. The general principles of law, especially those widely accepted by the EU and inserted in the Charter of Fundamental Rights, provide an illustration of this interaction (Haberle 2003, p. 127). In sum, law should be understood nowadays as more than a collection of rules of conduct imposed by the legislator and judges' adjudication in the classic positivist definition. Particularly in the field of science and society the legal system involves a rising number of soft-law instruments, participatory mechanisms and advisory committees and panels.³

Yet, the definition of legal principles and legal rights is not always easy to make. Dworkin argued that principles are standards to be observed because they constitute requirements of 'justice or fairness or some other dimension of morality' (Dworkin 1977, p. 22). Habermas observed that while legal principles 'have a deontological sense', values that are embraced by the law are teleological (Habermas 1996, p. 255). In turn, Alexy defined principles as 'norms commanding that something must be realized to the highest degree that is actually and legally possible' (Alexy 1992, p. 145). Thus, the most obvious distinctive feature of a *legal* principle is its 'juridical' quality, opposing a merely ethical or social one, meaning that it must be included in a legal norm.

Legal principles, also conceptualised by some legal positivists as imperfect norms, provide general normative guidelines to be developed through legal norms, properly speaking (Zagrebelsky 2002, p. 870). Thus, both principles and norms are more or less general instructions with respect to expected behaviour of defined groups or the expected performance of a specific activity.

A deeply interrelated concept with that of legal principles is that of legal rights. *Legal rights* can be construed as freedoms to act or refrain from acting or entitlements to be acted upon or not acted upon that are provided by law. As societies become more complex, more and more rights, including freedoms, translate into obligations addressed to states or to third parties to ensure that their content is fulfilled. Hence both principles and rights as normative and authoritative statements translate particular values into goals for the legal order to achieve. The EU Charter on Fundamental Rights offers a paradigmatic example of a human rights protection system that combines principles and rights (including freedoms). The singling out of *principles* and *rights* in the Charter can easily be ascertained from a

³ Accordingly, the notion of law used in this report will encompass both binding legal instruments of European law, i.e. regulations and directives of the European Council and the European Parliament and decisions of EU institutions; and soft law that is not formally binding and may emanate both from EU institutions and self-regulatory entities, for example, professionally-based codes of conduct.

simple reading.⁴ Indeed, one may generally accept that when the Charter declares that specific values should be protected or specific goals should be pursued⁵, it is asserting a principle, whereas when the individual is referred to by the Charter a right is being stated⁶ (Soares 2002, p. 69). Article 51/1 of the Charter, according to which EU institutions and Member States shall '**respect the rights**' and '**observe the principles**', while not differentiating these concepts neatly, renders clear the common responsibility of public authorities 'to promote the application' of both principles and rights. Further clarification comes out from the Explanations of the Charter (EU 2007b). According to this document, principles may be implemented through legislative or executive acts, and shape the ECJ and national court's interpretation or review of those acts. However, they contrast with rights since they do not 'give rise to direct claims for positive action by the Union's institutions or Member States authorities'. This distinction should not be meant to imply that principles are weaker since European institutions are required to comply with such principles and can even be judicially responsible for not complying with them.

For the purposes of the present analysis, an additional distinction should be taken into account: law and regulation. While *law* can be identified with general and fundamental principles and rights, *regulation* is meant to be control exercised by a public agency over activities that are valued by a community. Public regulation involves policy choices and in that sense it represents a 'materialization of the law' (Habermas 1986). As indicated above, the legal order develops in a gradual manner from the initial generic framework set by principles and rights, normally stated in treaties and constitutions, progressively narrowed to public regulation. As pointed out already, regulatory institutions and procedures, e.g. for licensing or authorisation, and monitoring of certain economic or social activities, and the way regulatory competencies and powers are distributed among public bodies and other entities, both national and European, including the provision of consultative and participative mechanisms, may facilitate or otherwise constrain the receptiveness of the regulatory system to values as they are perceived in or by society.

Hence, while assessing the translation of values into European law and regulation attention should be paid to the channels opened by law for stakeholders and civil society to have a say in the regulatory process and by this means expressing 'their' most-prized values and ultimately shaping the value system brought into law or regulation. To what extent are

⁴ Examples are Article 13, 'The arts and scientific research shall be free of constraint', and Article 37, 'A high level of environmental protection and the improvement of the quality of the environment must be integrated into the policies of the Union and ensured in accordance with the principle of sustainable development'.

there 'platforms of dialogue on values', as recommended by the European Commission (EC 2005, p. 20)?

3. Values in European law addressing biometrics

As pointed out already, principles and rights provide us with the main doorways for acceding to values embedded in the law. Principles play a critical role in respect of emerging sciences and technologies since they can more easily accommodate the dynamics of scientific and technological progress.

Since the protection of individual or groups' rights is carried out through principles and norms that are likely to limit or constrain scientific activities or the development or employment of technology, there is scope for conflict between the interests or rights of S&T developers and users and those of individuals or society. The EU legislator often seeks to balance these opposing interests and rights, namely, research and technological development understood as an interest of the EU and the rights of individuals or citizens. Often, this contradiction is presented as opposing ethical to market values. But the issue is more complex than that. The freedom of research, for example, may be regarded as a component of the fundamental freedoms of thought and of speech; yet, it may also be related with free enterprise.

Against this background, which values are being summoned by European law and regulation shaping the development and deployment of biometrics? Beyond the general provisions of the Charter of Fundamental Rights, how are the relevant conflicting principles and rights being tackled by EU regulation? And what does that tell us about the 'value system' embedded in European law on science and technology (S&T) more generally?

Biometrics is a technique that relies on human characteristics to verify the identity of an individual. Face features, fingerprints, hand impressions, iris recognition or DNA are such physiological features that can be used in biometrics. Biometric technology can thus be defined as identifying individuals by using their biological or behavioural characteristics⁷.

Lately biometric technology turned out to be one of the central pieces of national and international security and immigration policies in Europe and is becoming also increasingly important economically as it is more and more employed to control access of workers, students, and other categories of people in various organisations (IPTS 2005, pp. 80-87). This technology rose to the centre of techno-juridical and techno-political debates

⁷ Physiological and behavioural characteristics (voice, signature, etc.) are sometimes differentiated as biometrical indicators, but the distinction is not a peaceful one.

of our era following the '9/11' when security measures became more tightened worldwide approaching the idea of a 'maximum security society' (Marx 1988)⁸.

Liberty, security and privacy are the most obvious values challenged by biometrics. But others are at stake as well, namely dignity and democracy. In fact, alongside the growing use of biometrics, concerns about civil liberties and the values underneath have amplified. The dichotomy between security, on one hand, and freedom, privacy and even human dignity, on the other, as well as the classic and broader confrontation between security and democracy came up in that connection. As a matter of fact, the growing use of information and surveillance technologies brings about a higher degree of complexity of value conflicts, and maybe even novel value conflicts. According to De Hert (2005b, p. 38), 'there is a need to establish both common principles and language of privacy for biometrics, including principles such as equality of access to the network; absolute accuracy of targeting by surveillance systems; systems to ensure the accuracy of the data held within the surveillance systems; mechanisms for making good the bad, inaccurate or changed data; systems to protect individuals from their inclination to trade their own privacy'. Some authors have called attention to a maybe upcoming 'surveillance society' largely nurtured by unawareness of citizens themselves about the corresponding risks (Marx 2008). They fear that the current legal system may give too much leeway to new technological developments incepted without proper interrogation from and altering to a human rights perspective.

When collecting biometrical data, the physical integrity of the subject should be secured against any harm, it has also been argued. Beyond privacy, intimacy and the emotional integrity of the person together with the dignity and respect for the person's 'decorum' need to be considered as well (CNPD 2004, p. 2). Biometric characteristics represent a part of people's individuality and are intimately linked to the persons themselves (CNPD 2004, p. 1).

Hence the values interfered with by biometrics can be divided in two sets: security and related rights, on the one hand, and liberty, privacy, intimacy and related rights (namely, data protection), on the other. The right to conduct a business and the freedom of research also play a part in the biometrics' 'rights balance' to the extent that development and economic investment in biometric technologies are recognised as legitimate rights.

⁸ This comes out from a number of EU documents such as the proposal of September 2003 on a uniform format for visas and residence permits and the proposal of February 2004 for a regulation on biometrics in EU citizens' passports, COM(2004) 116 final. However, it has also been pointed out that the 9/11 justification fails partly since most of the terrorists travel with their own valid passports (Hornung 2007, p. 259).

However, the official European stance on this complex matter rests on the assumption that security and civil liberties can be easily compared and conciliated (Liberatore 2007, p. 114). The argument has also been built around the idea that biometrics can be used to guarantee privacy (when used to reduce the access of a room or a computer through a fingerprint recognition technique to a single person for instance) countering the idea ‘more security, less privacy’ (Hornung 2007, p. 249). Also ‘privacy and data protection should not be characterised as a zero sum gain where an individual gain means a societal loss or vice-versa’, it is stated in a report published by the EC (Robinson et al. 2009, p. 16). This idea has been underlined in other policy documents reflecting the European perspective: opposing an individual value such as liberty against a rather more community-oriented value such as security does not necessarily mean that an individual value is being sacrificed in the name of the society – in fact, instead of a ‘zero sum game’ the official description points to a ‘win-win’ situation. This understanding has reminiscences with the theoretical approach considering rights and policies to be, not exclusive, the first concerning the individual and the second society (Dworkin 2002, p. 23), but interchangeable concepts instead (Atienza 1991, p. 106).

Decision N° 1982/2006/EC approving the 7th Framework Programme on Research and Development follows the same line of reasoning when it states that ‘security in Europe is a *precondition of prosperity and freedom*’⁹. In fact, the EU is actively promoting biometrics and other security technologies as part of EU research and development policy.

Article 6 of the Charter of Fundamental Rights goes even further in this conciliatory move since it addresses *liberty and security* as part of a *unique right*. But why have liberty and security been treated in an integrated manner in the Charter? Should they be regarded as the two faces of the same coin or rather as conflicting principles or rights?¹⁰

One may possibly intuit that this option may have been part of a political stratagem to render a novel EU security policy more acceptable to the public opinion.

The use of biometrics in EU citizens’ passports in particular was a consequence of a USA already engaged in the ‘war against terror’. Referring to the ‘rush’ to using biometrics within Europe, a EC-sponsored report noted, ‘The driving force has of course been *entirely political* and aimed at demonstrating some sort of response to terrorism and national

⁹ Decision N° 1982/2006/EC, L412/26.

¹⁰ Biometrics raise other issues, namely: concerns for power accumulation, and about further use of existing data; concerns about specific threats proper to biometrics; about the use of this technology in the private sector and about the inability to protect individuals from their inclination to trade their own privacy and concerns for costs (De Hert 2005, p. 37; Marx 2008).

security, while simultaneously introducing vastly increased powers of law enforcement activity.’ (IPST 2005, p. 20).

Yet, the single right option was not free from controversy during the negotiations which led to the adoption of the Charter. There were proposals to separate both concepts and proposals to delete the reference to ‘security’ that did not come through mainly because this is the phrasing of the European Convention of Human Rights (Charte 4360/00, Convent 37, p. 8).

A look at the EU legal framework applicable to the use of biometrics leads us to two results only: Council Regulation (EC) N° 2252/2004 of 13 December 2004 on standards for security features and biometrics in passports and travel documents issued by Member States; and Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, which is rendered applicable with regard to the personal data to be processed in the context of passports and travel documents by Regulation N° 2252/2004 (Article 4 and Whereas 8).

Remarkably, Regulation N° 2252/2004 is basically a technical normative text, rather than a value or rights-oriented one.¹¹

Its object centers on the technical specifications and standards for passports and travel documents, which the regulation seeks to harmonise across the EU. Yet, the right to security is somehow privileged given the emphasis placed on biometrics as a requisite for more secure and reliable identification of holders and protection against falsification or other fraudulent use.

From the fundamental human rights’ angle the European legislator has limited its consideration to biometrical data protection, thus disregarding the implications of the employment of biometrics on the individuals’ intimacy component of privacy and on the exercise of freedom and democracy more generally. As an IPST report (IPST 2005, p. 20) acknowledges, *‘principles of privacy and data protection have been discarded wholesale.’* And, the report goes on, *‘If we are not careful, we shall find ourselves headed towards a global police state, heavily manipulated by one or two strong governments. This will not make for a better world.’*

Conceiving security and freedom as merged into one single right may no doubt help reducing the scope for these rights’ conflict. Potential consequences of spread of the use of surveillance technologies for democracy also tend to be presented by EU political discourse

¹¹ Article 1 of Regulation N° 2252/2004, amended by Regulation N° 444/2009.

on a positive, rather than negative tone, security technologies being portrayed as means to protect our democratic systems against external threats.

In reality, biometrics is, in our view, at the centre of an actual conflict opposing *liberty* in the sense of free movement of persons or security as it implies strengthened border or other controls of people. Moreover, growing use of biometrics as a surveillance technology risks impinging on important personal values such as privacy and intimacy, as well as affect the workings of democratic and free societies given the behavioural constraints that it may further. In his Opinion delivered on the Case C-137/05, Advocate General Trstenjak acknowledged the problems caused from the fundamental human rights' angle by Regulation 2252/2004, though not developing her argument since the United Kingdom did not challenge the regulation on grounds of human rights violation.¹² The European Data Protection Supervisor also recognised that '*there can be no doubt about the importance of a strong mechanism for the protection of fundamental rights of the citizen' regarding biometrics.*'¹³

In sum, the employment of biometrics *per se* has not been truly questioned or debated. The EU focused its regulatory action on technical standardisation of biometrical applications to passports and travel documents. From the substantive legal standpoint, attention was indeed centred on biometrical data protection.

In fact, the biometrical process involves capturing and collecting 'information relating to an identified or identifiable natural person' which is one 'who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity', according to the EU data protection directive (Directive 95/46/EC, Article 2, a.). Hence, personal data protection represents an important facet of biometrics technology's regulation.

Applying the data protection regime to biometrical data as to any other category of personal data implies the presumption of the legitimacy of biometrics. Besides, data protection legislation allows the data processor to be the first arbiter of the need to process biometrical data, raising doubts about how the requirements of procedural justice are tackled. Directive 95/46/EC balances between different policy goals, interests and rights, namely those of public or private organisations in the use of personal data, and

¹² Opinion of Advocate General Trstenjak, delivered on 10 July 2007, Case C-137/05, United Kingdom v Council of the European Union [2008] ERC I-02245, paragraph 126.

¹³ Opinion of the European Data Protection Supervisor on the Communication from the Commission to the European Parliament and the Council on an area of freedom, security and justice serving the citizen (2009/C 276/02), p. 9.

those of the data subjects in the good use and protection of such data. The data controller must ensure compliance with a series of principles, including the principles of data quality and the principle of transparency (Article 6). These principles echo in Article 4, 2 and 3 of Regulation N° 2252/2004.

The data subjects have the right to know who the data controller is, the purpose of the processing, the recipient of the data and to have inaccurate data rectified (Articles 10 and 11). The directive contains strengthened protections concerning the use of *special categories of personal data* relating namely to racial or ethnic origin, religious or philosophical beliefs, health and sex life (Article 8). Given its hypersensitive character, biometrical data may be regarded nowadays as an additional category of personal data deserving special protection. The Article 29 Data Protection Working Party, acknowledging the increasing collection of biometrics, considered that biometrical data should only be used in a subsidiary way, that is, whenever ‘less intrusive material’ does not allow the same effect (Article 29 Data Protection Working Party 2009, p. 27).¹⁴

However, restrictions to personal data protection may apply in order to safeguard national security, defence, public security, prevention and criminal investigation, economic or financial interests of states, rights and freedoms of others (Article 13), a provision that finds its inspiration in Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms.

This ‘security exception’ is stirring recent developments of EU policy. In March 2010, the EC presented a ‘Proposal of a Regulation for the creation of an Agency for the operational management of large-scale IT systems in the area of freedom, security and justice’ covering matters related to checks on persons at external borders, illegal immigration and illegal residence and asylum.¹⁵ Yet, this initiative did not go without reservations by the European Parliament about the ensuing perils for human rights (EP 2005).

All in all, biometrics has been mostly framed in EU law and policy in light of security values and related principles and rights to the detriment of the consideration of its implications for the exercise of freedom and democracy. Besides, the insufficiency of the procedural arrangements that involved the adoption of biometrics in passports from the point of view of social involvement in this respect has been observed:

¹⁴ The EU Charter of Fundamental Rights clarifies the status of the protection of personal data as a fundamental right. Besides, Article 16 of the Treaty on the Functioning of the European Union extends the implementation of the data protection principles and rights to EU institutions. Will this raising of the rights to privacy and data protection to a fundamental right status may affect their balance vis-à-vis the rights of data controllers, one may wonder.

¹⁵ COM(2010) 93 final, 19.03.2010.

'It is time also to bring citizens squarely into the debate. Not by carefully manipulated opinion polls, but by honest and open public discussion. (...). The dialogue to date has been heavily influenced by commercial interest and political aspirations. There has been remarkably little genuine consultation with citizens on a matter which will have a significant impact upon society.' (IPTS 2005, p. 21).

It is also being recognised that existing data protection rules on the use of biometrics 'lack normative content and ethical debate' (IPTS 2005, p. 16). Looking into the future, one may thus conclude, in a positive tone, with the expectation that the way is open for a genuine reconsideration of the current legal framework on biometrics.

4. Final remarks

The importance assigned in recent years by the EU to the promotion of the development and use of biometrics offers an opportunity for scrutinizing the underlying values, as well as the balancing of fundamental legal principles and rights.

The introduction of biometrics as a security or surveillance technology has not been questioned on grounds of potential risk for human rights or other fundamental EU values even at a time when a Charter of Fundamental Rights has been formally adopted. Concerns expressed by a number of analysts, including in reports on the matter prepared for the European Commission, on potential implications for the exercise of freedom and more generally for the workings of democratic societies, have been discarded. Quite the opposite, that biometrics has been regarded a legitimate and even desirable technological innovation by the EU is apparent from the fact that the EU is actively encouraging its research and development under the 7th framework programme.

The introduction of biometrics in passports and travel documents in the EU was, as noted, a consequence of a political decision adopted under pressure by the USA. Once that political decision had been taken, the EU pursued its conventional, somewhat instrumental path towards mere technical standards harmonisation.

Human rights considerations were formatted as a *personal data protection* issue only, resembling other data digital applications to be addressed under the existing data protection regime, thus neglecting, once again, the special sensitivity of biometrical data from the privacy and intimacy standpoint.

By the same token, expectations opened up by the Charter on a renewed and stronger responsibility of EU institutions to '*promote the application*' of the fundamental principles and rights ends up somewhat frustrated.

References

Alexy, Robert (2010), *A Theory of Constitutional Rights*. Oxford: Oxford University Press.

Alexy, Robert (1992), 'Rights, Legal Reasoning and Rational Discourse', *Ratio Juris*, vol. 5, n. 2, pp. 143-152.

Alston and Weiler (1999), "An 'ever closer union' in need of a human rights policy", in Alston (Ed.), *The EU and Human Rights*. Oxford: Oxford University Press.

Article 29 Data Protection Working Party (2009), 'The Future of Privacy, Joint contribution to the Consultation of the European Commission on the legal framework for the fundamental right to protection of personal data', 02356/09/EN, WP 168, adopted on 1 December 2009.

Atienza, Manuel; Juan Ruiz Manero (1991), 'Sobre principios y reglas', in *Doxa: Cuadernos de Filosofía del Derecho*, 10, pp. 101-120, http://www.cervantesvirtual.com/servlet/SirveObras/12482196462352624198846/cuaderno10/doxa10_04.pdf.

CNPD - Comissão Nacional para a Protecção de Dados (2004), Parecer 'Princípios sobre a utilização de dados biométricos no âmbito do controlo de acessos e de assiduidade', <http://www.cnpd.pt/bin/orientacoes/principiosbiometricos.htm>.

Council of Europe (1950), *Convention for the Protection of Human Rights and Fundamental Freedoms*, Rome.

Council Regulation (EC) No 2252/2004 of 13 December 2004 on standards for security features and biometrics in passports and travel documents issued by Member States.

Curzon, Stephen (2009), 'Fundamental rights and the Internal Market. The state of affairs following Schmidberger & Omega', in *Les droits fondamentaux dans l'Union européenne*, Joël Rideau (dir.), Bruxelles: Bruylant, pp. 109-129.

Directive 95/46/EC of the European Parliament and the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

Dworkin, Ronald (2002), *Sovereign Virtue, The Theory and Practice of Equality*. Cambridge: Harvard University Press.

Dworkin, Ronald (1977), *Taking Rights Seriously*. London: Duckworth.

European Commission (2004), Proposal for a Council Regulation on standards for security features and biometrics in EU citizens' passports, COM(2004) 116 final.

European Commission (2005), *Social Values, Science and Technology*. Report of the Science Policy Research Group (Coord. G. Gaskell). Brussels: European Commission.

European Data Protection Supervisor (2009), 'Opinion on the Communication from the Commission to the European Parliament and the Council on an area of freedom, security and justice serving the citizen', 2009/C 276/02.

European Parliament (2005), Resolution on the proposal for a Council regulation on standards for security features and biometrics in EU citizens' passports, *Official Journal* 208 E, 25/08/2005 P. 0050 – 0054

European Union (2007), Charter of Fundamental Rights of the European Union, 2007/C 303/01.

European Union (2007), Explanations relating to the Charter of Fundamental Rights, 2007/C 303/02.

Haberle, Peter (2003), *El Estado Constitucional*. México: Universidad Nacional Autónoma de México, Instituto de Investigaciones Jurídicas.

Habermas, Jurgen (1996), *Between Facts and Norms, Contributions to a Discourse Theory of Law and Democracy*, Cambridge: The MIT Press.

Habermas, Jurgen (1986), *Law and Morality*, The Tanner Lectures. Cambridge: Harvard University.

Hert, Paul de (2005), 'Biometrics: legal issues and implications', http://cybersecurity.jrc.ec.europa.eu/docs/LIBE%20Biometrics%20March%2005/LegalImplications_Paul_de_Hert.pdf.

IPTS - Institute for Prospective Technological Studies (2005), 'Biometrics at the Frontiers: Assessing the Impact on Society', Joint Research Centre, European Commission, http://ec.europa.eu/justice_home/doc_centre/freetravel/doc/biometrics_eur21585_en.pdf.

Liberatore, Angela (2007), 'Balancing Security and Democracy, and the Role of Expertise: Biometrics Politics in the European Union', *European Journal on Criminal Policy and Research*, No. 13, pp. 109-137.

Marx, Gary T. (1988), 'La société de sécurité maximale', *Déviance et Société*, Vol. 12, No. 2, pp. 147-166.

Marx, Gary T. (2008), 'Vigilância soft – o crescimento da voluntariedade obrigatória na recolha de dados pessoais. ó amigo, empresta-me uma amostra de DNA?'. In C. Fróis (ed.), *A Sociedade Vigilante*, Lisbon: Imprensa da Ciências Sociais, pp. 87-109.

Morin, Edgar (2004), 'L'éthique de la complexité et le problème des valeurs au XXI^e siècle', in *Où Vont les Valeurs?*, Jerome Bind (dir.), Paris : Éditions Unesco/Albin Michel.

Robinson, Neil, et al. (2009), *Review of the European Data Protection Directive*, Rand Europe.

Tsakyarakis, Stavros (2008), 'Proportionality: An assault on Human Rights?', Jean Monnet Working Paper 09/08, <<http://centers.law.nyu.edu/jeanmonnet/papers/o8/o80901.pdf>>.

Von Bodgandy, Armin (2000), 'The European Union as a Human Rights Organization? Human Rights and the core of the European Union', *Common Market Law Review* 37, pp. 1307–1338.

Zagrebelsky, Gustavo (2002), 'Diritto per: valori, principi o regole? (a proposito della dottrina dei principi di Ronald Dworkin)', *Quaderni fiorentini per la storia del pensiero giuridico moderno*, Vol. 31, pp. 865-897.

Case law

Opinion of Advocate General Trstenjak on the Case C-137/05, United Kingdom of Great Britain and Northern Ireland v Council of the European Union [2008] ECR I- 02245.

Case C-137/05, United Kingdom of Great Britain and Northern Ireland v Council of the European Union [2007] ECR I-11593.

Selected links

• Art.29 Data Protection Working Party
http://ec.europa.eu/justice_home/fsj/privacy/workinggroup/index_en.htm

• Centre for Science, Society and Citizenship <http://www.cssc.eu/index.php>

• Council of Europe http://www.coe.int/t/e/legal_affairs/legal_co-operation/Data_protection/

• Electronic Privacy Information Centre (EPIC) <http://epic.org/>

• European Biometrics Forum <http://www.eubiometricsforum.com/>

• European Parliament Committee on Civil Liberties, Justice and Home Affairs
http://www.europarl.europa.eu/committees/libe_home_en.htm

• Privacy International <http://www.privacyinternational.org/>

• Science and Technology Options Assessment
http://www.europarl.europa.eu/stoa/default_en.htm

• Statewatch <http://www.statewatch.org/>