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## 1. Introduction

The experience of globalization and the development of science and technology led to a widespread debate over the role of law, the idea of governance, the participation of civil society and the emergence of alternative forms of regulation such as soft law<sup>1</sup>.

The concept of “soft law”, in contrast with “hard law”, is commonly applied to a wide set of formally non-binding normative instruments. Generally it has been associated with different fields, from international law to the technical provisions of codes of conduct self-enforced by

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<sup>1</sup> The regulation of science and technology has been accompanied by the phenomenon of new technologies being used as regulatory tools (DNA profiling, CCTV captures, etc.), in other words, ‘regulatory targets becoming regulatory tools’ (Brownsword 2008, 23) (cf. Brownsword; Yeung 2008, 49-218).

professionals and industry. Broadly speaking, the concept can include guidelines, recommendations, codes of conduct, declarations, communications, resolutions, either from governmental or non-governmental entities. For example, until 2009 and the approval of the Treaty of Lisbon, the Charter of Fundamental Rights of the European Union could be seen as having the nature of a soft law instrument. One of the main features of soft law is precisely its normative nature, although without binding force, as opposed to a merely ethical or moral nature (Andorno 2007).

In the European Union, where the *soft law* approach has visibly expanded<sup>2</sup>, it covers different fields, such as finance<sup>3</sup>, taxation and workers rights, and has spread in particular in the field of science and technology. In fact, the regulation of science and technology seems to be a fertile ground for soft law instruments.

The development of soft law started precisely in the international law arena, where traditionally non-binding yet normative instruments appeared as natural (Di Robilant 2006).

The setting of international relations has been as a fecund ground for debates on soft law and on the legal nature of international conventions, non-binding treaties and other agreements. Although these debates continue to stir the international arena<sup>4</sup>, a specific field of European soft law is emerging<sup>5</sup>. Mörth acknowledges, 'The interest (in soft law) in the late 1990s and in the early 2000s ... reflects the increasing awareness of globalisation and the importance of non-state actors but also how globalisation makes traditional law making more problematic when states are embedded in various formal and informal organisations. The concept of soft law fits nicely with the notion of international regimes and with the analysis of the EU as a system of multilevel governance' (2005, 4).

It is exactly the element of the legally binding force that distinguishes soft from hard law instruments, as expressed precisely in the terms 'soft' and 'hard' (Senden 2004, 112).

Soft law also appears sometimes side-by-side with the concept of self-regulation, as will be discussed below.

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<sup>2</sup> References to soft law in the context of European law began to appear timidly in the 1980s (Senden 2004, 109).

<sup>3</sup> An example is the Code of Ethical Criteria for the members of the Executive Board of the European Central Bank.

<sup>4</sup> On the binding character of international norms, see Thomas M. Franck (1990), *The Power of Legitimacy among Nations*, New York: Oxford University Press. A classic work on international public law is Pierre-Marie Dupuy; Yann Kerbrat (2010), *Droit international public*, 10th ed., Paris: Dalloz.

<sup>5</sup> In a different sense see EP Resolution: 'Community law may be distinguished from public international law by reason of the fact that it is binding, not only on States but on individuals' (EP 2007, paragraph H).

This paper focuses on the use of soft law by European Union institutions in science and technology-related areas. Based on a general survey of pertinent soft law instruments, we will try to pave the way for the exploration of:

- i) The *variety* of soft law instruments in light of the contexts of their use;
- ii) The *main motivations* for resorting to soft rather than hard law, and whether this choice can be regarded as a requirement of the nature of the matter or of the subjects to be regulated, a preparatory stage leading to hard law or the result of a deliberate option of the legislator or the regulator not to impose strict constraints or limitations to particular activities;
- iii) How the *efficacy* of soft law can be evaluated in terms of behaviour control of its addressees, namely scientists and research institutions, technology developers and industry, as well as other stakeholders, including civil society organizations.

Relevant issues thus are the reasons for the increasing use of soft law in the fields of science and technology; and why these fields are seemingly more permeable to soft law instruments than others. In this connection, the paper will discuss *two working hypotheses*: first, that soft law has perhaps acquired a special relevance in these areas in view of their ethical implications (e.g. in biology or biotechnology, information or security technologies); second, that soft law may offer interesting opportunities to move from government to governance approaches to decision-making.

It is indeed commonly believed that soft law may be a more adequate way than hard law of dealing with the ethical dimensions of science and technology. Since ethics is largely based upon weighting of *prima facie* principles and considerations that are mostly context dependent, soft law may accommodate these factors more easily than hard law. Moreover, it has been admitted, soft law constitutes an important aspect of the 'new governance phenomenon' in the European Union (Trubek 2005, 1), and one that has constantly been increasing in the past decade (Graça 2008, 127). In fact, soft law has been typically associated with the idea of governance involving 'horizontal networks and authority relations, flexibility and voluntary rules', as opposed to hard law, which is associated with the traditional notion of government (Mörth 2005, 2). Yet, governance does not exclude necessarily hard law. One issue that deserves to be discussed in the context of governance tools for science and technology is precisely the question if soft law can better 'accommodate the various constituencies that make up an ethical plurality' (Brownsword 2008, 32). Another point deserving further attention is the choice to regulate or not, through hard or soft law, a specific

technology (Kirby 2008, 375). The absence of regulation is not neutral, nor is the option for hard or soft law.

## 2. Soft law in the European legal system

### 2.1. The variety of soft law instruments

Various definitions of soft law have been proposed. Lawyers are sometimes 'more inclined to treat soft law as an analytical concept whereas the social scientists tend to treat it as an empirical phenomenon' (Mörth 2005, 6). A straightforward concept states that soft law concerns 'rules of conduct which, in principle, have no legally binding force but which nevertheless may have practical effects' (Snyder 1993, 198). Another definition of soft law points to 'rules of conduct that are laid down in instruments which have not been attributed legally binding force as such, but nevertheless may have certain (indirect) legal effects, and that are aimed at and may produce practical effects' (Senden 2004, 112). An additional description points to soft law as a 'rule issued by a law-making authority that does not comply with constitutional and other formalities that are necessary for the rule to be legally binding' (Gersen; Posner 2008, 6). Finally, an highly structured concept describes soft law as 'the rules of conduct that find themselves on the legally non-binding level (in the sense of enforceable and sanctionable through forms of responsibility and accountability) but which according to the intention of their authors do embrace a legal scope, which has to be further defined in each case (Wellens; Borchardt 1989, 274).

In short, soft law generally consists of rules of conduct laid down in instruments with some legal effect, but without binding force, and aims at some practical effect (Senden 2005, 23).

Article 288 TFEU addresses recommendations and opinions confirming their status as legal acts without binding force (Senden 2004, 23, 107).

The lack of legal binding force is often perceived as the distinctive feature of soft law. In the European context this is not, however, an undisputed statement. The European Parliament affirmed that 'the distinction between *dura lex/mollis lex*, being conceptually aberrant, should not be accepted or recognised' (EP 2007, paragraph B) and that 'so-called soft law instruments, such as recommendations, green and white papers or Council conclusions, do not have any legal value or binding force' (EP 2007, paragraph C). The Parliament added that 'such instruments, which can be used as interpretative or preparatory tools for binding legislative

acts, should neither be treated as legislation nor be given any norm-setting effectiveness' (EP 2007, paragraph M), being "soft law" merely a first stage leading to "hard law". But that has not been the position held by the Commission and, to a certain extent, by the European Court of Justice, which has recognised legal effects to instruments of soft law, such as the Communication on the Precautionary Principle. The European Parliament acknowledged that 'there is currently a dispute as to how to make the regulatory function of the European Union more efficient with regard to both "soft law" and "hard law"' (EP 2007, paragraph F) and recognised that 'none the less, the Court has held that [recommendations] "cannot ... be regarded as having no legal effect. The national courts are bound to take recommendations into consideration in order to decide disputes submitted to them ..."' (EP 2007, paragraph R referring to Case C-322/88 Grimaldi [1989] ECR 4407, paragraph 18).

A quite distinct concept is self-regulation meaning the processes of adopting common guidelines by non-governmental organisations, economic or social partners amongst themselves (Senden 2005, 11, 12). Although it may receive some kind of impulse from European authorities, it has a more 'independent' character and fits perfectly in the idea of a 'bottom up approach' (Senden 2005, 12).

In this vein, expressions of soft law in the EU legal system may range from resolutions, recommendations, opinions, communications, and white and green papers from EU institutions to codes of conduct or codes of practice from either EU bodies or non-governmental entities operating within the system. Generally, the growing recourse to soft law in the EU can be linked to the objectives underlying the guidelines contained in the European Commission's White Paper on European Governance, published in 2001. The White Paper states the aim to 'combining formal rules with other non-binding tools such as recommendations, guidelines or even self-regulation' as a means towards a 'less top-down approach' in EU law making (EC 2001, 4, 20, 22).<sup>6</sup>

In this connection some distinctions are in order. Instruments and non-binding policy documents arising from the European institutions do not always constitute soft law. But if this statement seems obvious, the distinction between what constitutes soft law or not is less so. The same type of instrument, a communication or a recommendation, arising from the same institution, the European Commission, for instance, may be considered soft law or a mere political declaration. The distinction based on the origin or the nature of the document does not help much in this situation. Indeed, soft law instruments must be analysed on a case-by-case basis, taking into account the purpose and objective of the particular instrument, namely

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<sup>6</sup> Cf. Linda Senden (2005), 'Soft law, Self regulation and Co-regulation in European Law: Where Do They Meet?', *Electronic Journal of Comparative Law*, vol. 9.

if it performs a pre-legislative function or just a strategic guidance, or if it has a normative though not binding character, stating principles, norms or setting some interpreting framework. A strong hint of what constitutes soft law can be traced to the European Court of Justice and to hard law instruments when they remit to soft law instruments.

Soft law may relate with hard law in one of three ways: it can have a pre-law function (preparatory and informative instruments such as green papers, white papers or action programmes), a post-law function (interpretative and decisional instruments), or a para-law function (steering instruments, such as recommendations) (Senden 2005, 24).<sup>7</sup> Soft law is also employed as part of co-regulation involving both soft law and a hard law framework setting limits and objectives of the soft law instruments (Senden 2005, 22).

## 2.2. Self-regulation

While soft law is more often than not regarded as arising from the public sphere, self-regulation is generally associated with the private sector. Yet, soft law can be regarded as having a close relation with self-regulation. The blurring of the borders between public and private, and the notion that governance entails the idea of authority shared between private and public and the participation of a wide range of actors can give rise to doubts in relation with this simple division. As one political scientist puts it 'Law can be regarded as the very essence of public authority. But law is also decided by other actors and if we label these regulations as non-law we tend to only reproduce the traditional dichotomisation between the public sphere and the private sphere' (Mörth 2005, 6)<sup>8</sup>. However, withdrawing the concept of binding force and at the same time the concept of law, in the classical sense of rules with legal scope arising from a legitimate authority, may raise difficulties for defining what soft law is, namely its utility when a very open concept allows the Communication from the Commission on the Precautionary Principle and a self-regulatory code of conduct from a certain group of professionals be placed under the same umbrella.

Self-regulation is defined in the 'Inter-institutional Agreement on Better Law Making' as 'the possibility for economic operators, the social partners, non-governmental organisations or

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<sup>7</sup> Some instruments can have more than one function, such as the Commission communications, that sometimes give guidance to the application of existing Community law but can also serve to prepare future Community law (Senden 2005, 23, 24).

<sup>8</sup> On the notion of 'public responsibility' related with the private sector see Mireille Delmas-Marty and Olivier Maurel (2009), 'L'appel à une nouvelle responsabilité des entreprises', in Commission nationale consultative des droits de l'homme, *La responsabilité des entreprises en matière de droits de l'homme*, Paris : La documentation française.

associations to adopt amongst themselves and for themselves common guidelines at European level' (Inter-institutional Agreement 2003, 3)<sup>9</sup>.

Self-regulatory instruments are frequently used by private actors, such as S&T professionals and industry as self-imposed rules of conduct. In science and technology, this type of instruments – codes of conduct, codes of practice, resolutions, etc. – are common because often the professionals are dealing with novel areas that entail new risks. The Internet provides a paradigmatic example of exhaustive self-regulatory instruments (Monroe; Verhulst 2005). But self-regulation requires the contributions from both the public and the private spheres: even if self-regulation is mainly the concern of private interests, 'the organisation of these interests by the partners ... cannot be done in a way that might appear damaging to the public interest' and it must take place in an atmosphere where fundamental values are respected (EESC 2005, 19).

Codes of conduct constitute a paradigmatic example of S&T self-regulation. The European Parliament, in the Resolution where it openly criticizes soft law, acknowledges that 'codes of conduct are important elements of self-regulation' (EP 2007, paragraph 12).

When resorting to law is limited, for reasons such as freedom of research, codes of conduct can constitute a useful way to regulate matters like scientific fraud, misuse or misconduct: 'In the relationship between citizens, society and science the issue of possible professional and/or ethical misconduct by scientists also plays a role. While both professional misconduct and mistakes made in good faith by scientists can be uncovered and punished largely by means of self-regulation by science itself (...), the issue of ethical misconduct goes to the core of the relationship between society and science' (EESC 2001, paragraphs 4.9, 4.9.1). But codes of conduct have also 'helped to establish codes of ethics', 'supported where appropriate by the social partners of the sector' (EESC 2005, 13).

Codes of conduct have developed extensively to cover a wide number of areas in the European Union. Apart from the 'traditional' codes of conduct set by multinationals and the professional and sectoral codes<sup>10</sup>, partially due to globalised free trade, there has been an increase in the

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<sup>9</sup> See also the Information Report adopted by the EESC in February 2005 on the *Current state of co-regulation and self-regulation in the Single Market* CESE 1182/2004 fin of 10.02.2005, 11. A useful database with self and co-regulation initiatives can be found in the European Economic and Social Committee website: <http://www.eesc.europa.eu/?i=portal.en.self-and-co-regulation-enter-the-database>.

<sup>10</sup> These codes of conduct include frequently codes of ethics addressing fundamental social values or the commitment to comply with shared principles. They are often set according to the guiding principles drawn up by the OECD or the code of conduct for multinationals from the European Parliament (Howitt report, January 1999) (EESC 2005, 16, 17).



codes addressed to consumers and in the area of environmental protection (EESC 2005, 16, 17).

European law recommends in different situations the enactment of codes of conduct. One example is Decision 2011/12/EU stating that the European Scientific Council shall adopt 'a code of conduct on confidentiality, potential conflict of interest, and processing of personal data' (EC 2011, Article 1, no 5). The Green Paper on Bio-preparedness poses some relevant additional questions: 'Should researchers in life sciences be obliged to adopt a professional code of conduct?' and 'Should the above-mentioned professional code of conduct be developed at EU level? If so, by whom?' (EC 2007, 14). A European Charter for Researchers and a Code of Conduct for the Recruitment of Researchers was the object of a recommendation from the Commission in 2005<sup>11</sup>. The European Charter for Researchers is a set of general principles and requirements such as research freedom and the respect of ethical principles<sup>12</sup>.

If, on one side, self-regulation can be a tactics to avoid regulation, on the other it allows for a more flexible and dynamic regulation in areas that are continuously shifting and evolving. Additionally, it 'leads to a sense of co-responsibility among economic and civil society stakeholders' (EESC 2005, 22).

### 2.3. Why soft law

Pros and cons of soft law have been debated. 'There are dangers of too strong reliance on soft law, especially when the authority of the design of particular soft law (like guidelines) is delegated to bodies that lack democratic control. One danger is that soft law may become a tool in the hands of a few powerful or privileged players that sidestep constraints of the legal process and that view it as a powerful alternative to lobbying elected representatives. Another problem is that soft law, due to the processes that may lead up to it, may contain imprecision and even contradicting demands, thus inviting users to defection.'

The European Parliament admitted that soft law does not 'provide full judicial protection' (EP 2007, paragraph D), brings 'confusion and insecurity' (EP 2007, paragraph N) and 'tends to create a public perception of "superbureaucracy" without democratic legitimacy, not just remote from citizens but actually hostile to them' (EP 2007, paragraph Y).

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<sup>11</sup> [http://ec.europa.eu/eracareers/pdf/am509774CEE\\_EN\\_E4.pdf](http://ec.europa.eu/eracareers/pdf/am509774CEE_EN_E4.pdf).

<sup>12</sup> 'Researchers should adhere to the recognised ethical practices and fundamental ethical principles appropriate to their discipline(s) as well as to ethical standards as documented in the different national, sectoral or institutional Codes of Ethics' (EC 2005, 11).

A set back of soft law instruments is precisely its 'loose' character for lack of binding force. However, soft law has a persuasive characteristic too, namely the threat that if it does not meet the objectives set by the European institutions, these can resort to hard law. This notion comes out clearly from the White Paper on Governance (when addressing co-regulation): the existence of soft law instruments does not preclude the possibility of hard law instruments if the latter do not reveal themselves effective (EC 2001, 21).

An additional difficulty may be the lack of transparency, since the form of elaborating and publicising soft law does not always take place through a mandatory clear process. This should be balanced against the increasing publication of EU soft law acts through the internet and the growing awareness of the need for consultation and dialogue, severely mitigating this problem (Senden 2004, 496).

'Soft law is seen sometimes as a smokescreen, disguising the real forces that drive scientific and technological development and innovation' (Value Isobars Description of Work, 36). However, 'The scientific and technological community places great importance on autonomy and often views soft law approaches as most promising in safeguarding ethical values.' (Value Isobars Description of Work, 36) In fact, soft law as an alternative or a complement to legislation offers more flexibility not only regarding procedures and approval requirements, but also because it does not have a binding nature. Additionally, soft law is often perceived as more adequate in contexts of social sensitivity, especially in S&T areas where values are at stake, than the immediate enforcement effect of hard law. Science and technology is an area where the 'caravan of controversy' moves on at a fast pace. Hard law when 'drafted too early may freeze in time the resolution of earliest controversies, which may later be regarded as immaterial or insignificant' (Kirby 2008, 373).

Soft law can also contribute to a broader direct participation in the context of consultative processes, leading to documents such as green or white papers, and in this sense, to enhance the legitimacy of European action (Senden 2004, 224). This aspect is mentioned in several Opinions from the European Economic and Social Committee.

Finally, it should be mentioned that soft law can be used to indicate directions in areas where the Union lacks jurisdiction. When the discussion on fundamental rights started in the European Union several voices manifested themselves against the adoption of a legal instrument since fundamental rights were not part of the Union's competence. In this particular situation, the Charter was felt as needed as a requirement for a coherent single European human rights policy, but in other instances soft law can be a disguise for bypassing the principle of legality, as mentioned by the European Parliament (EP 2007, paragraphs I, J).

### 3. Soft law and the regulation of science and technology

Soft law instruments can be singled out in different S&T areas, but some constitute paradigmatic examples, namely, nanotechnology, cloning, GMOs, biometrics and dual use technology.

#### 3.1. Selected S&T examples

##### 3.1.1. Nanotechnologies

As part of the effort to integrate the 'societal dimension' into research and development of nanotechnology the European Commission adopted a Communication including an action plan (EC 2009, 6) and a recommendation for a code of conduct in this field. The 'Commission Recommendation on a code of conduct for responsible nanosciences and nanotechnologies research' (EC 2008) offers an interesting example of soft law in S&T. First of all, it is a recommendation – a kind of soft law instrument – proposing another one, a code of conduct. The code aims at providing guidelines to 'all stakeholders' involved in nanotechnologies, 'Member States, employers, research funders, researchers and more generally all individuals and civil society organisations' (EC 2008, 5).

Stakeholders who adhere to the code 'should also be inspired, where applicable, by the principles set out in the Charter of Fundamental Rights of the European Union' and should ensure that 'N&N research is undertaken in the Community in a safe, ethical and effective framework' (EC 2008, 5).

The action plan for nanotechnologies adds that 'proposals that are considered for funding under FP7 and are ethically sensitive undergo a thorough ethical review. They are funded only if they address ethical issues adequately and meet the necessary Community and national requirements – for example the EU Charter of Fundamental Rights. Efforts are made to increase the researchers' awareness of the Commission's Code of Conduct.' (EC 2009, 6).

The European Parliament has recently sent out an appeal to manufacturers of nanomaterials to adhere to a code of conduct<sup>13</sup> since it 'is an essential instrument for safe, integrated and responsible research' (EP 2010, paragraph Z), bearing in mind that 'the likely convergence of nanotechnology with biotechnology, biology, cognitive sciences and information technology raises serious questions relating to ethics, safety, security and respect for fundamental rights' (EP 2010, paragraph Y). In the same paragraph the European Parliament also calls for a new opinion by the European Group on Ethics in Science and New Technologies as well as for a 'EU-wide public debate on nanotechnologies and nanomaterials and on the regulatory aspects of nanomaterials' (EP 2010, paragraph 23).

The concern about involvement of civil society when dealing with new technologies is one of the aspects associated with soft law. The involvement of stakeholders or the society in general is usually a feature of soft law instruments, such as green papers, in the form of consultations and public hearings among others. The European Parliament addressed this aspect in its Resolution on nanotechnologies calling on the Commission and Member States 'to pay special attention to the social dimension of the development of nanotechnology; ... considering that the active participation of the social partners concerned has to be ensured from the earliest possible stage' (EP 2010, paragraph 26). It should be pointed out, however, that these processes tend to be increasingly part of hard law too.

Emphasis on the ethical and human rights' implications of research and development in this field, as well as the importance of ensuring safety and security appear as the central motivations for the EC option to adopt the code of conduct.

### 3.1.2. GMOs

GMO regulation developed in the EU mainly through hard law instruments. But this technology also offers an illustration of the role that soft law can play in anticipating hard law instruments, either because the topics are sensitive and tend to be addressed first in a flexible non-binding manner, or due to the novelty of the subject-matter to be regulated.<sup>14</sup> A well known example of this kind of anticipatory move is the Asilomar Conference of 1975 when scientists drew up a

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<sup>13</sup> 'Calls for the application of a duty of care for manufacturers that wish to place nanomaterials onto the market; and calls on them to adhere to the European code of conduct for responsible nanosciences and nanotechnologies research' (10), European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials, (2010/C 184 E/18), P6\_TA(2009)0328.

<sup>14</sup> New developments in food law have seen the expansion of codes of conduct. The aquaculture industry constitutes another example of this self-regulatory trend: [http://www.piscestt.com/consumer/codes/feapintro\\_en.asp](http://www.piscestt.com/consumer/codes/feapintro_en.asp).

self-regulatory instrument<sup>15</sup> admitting the uncertainty of the impacts of genetic research and the necessity of regulating biotechnologies. In the European space, prior to Directive 90/220/EEC, genetic research and engineering was the subject of a number of written questions to the European Parliament but not of soft law instruments. There were two relevant resolutions though, a 'Resolution on the effects of the use of biotechnology on the European farming industry'<sup>16</sup> and a 'Resolution on the ethical and legal problems of genetic engineering'<sup>17</sup>.

Soft law may also play a complementary role to hard law as does the 'Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops', recognising that 'Member States need sufficient flexibility to take into account their regional and national specificities and the particular local needs' (EC 2010, paragraph 7) In this situation the balance takes place between European soft law and national hard law since Member states are the ones allowed to take measures to avoid the presence of GMO in other products (Directive 2001/18/CE, Article 26 a).

Another example of a code of conduct in this field is a recommendation from the Commission to 'Promote the adoption of a European-wide code of conduct concerning the contractual relationships between processors and distributors' concerning the agro-food industry and the food chain (EC 2009b, 10)

### 3.1.3. Cloning

In some sense, hard law parallels soft law in respect of cloning. The European Parliament's resolution on human cloning reflects the Parliament's recognition of the need to address a technology at an early stage of development, raising highly sensitive ethical dilemma. But there was an early rather broad consensus on the rejection of cloning for human reproductive purposes. This consensus underlay recourse to hard law in this area. Examples are Article 3 of the Charter of Fundamental Rights stating the principle of prohibition of reproductive of

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<sup>15</sup> Summary Statement of the Asilomar Conference on Recombinant DNA Molecules, 20 May 1975, [http://profiles.nlm.nih.gov/qq/B/C/G/D/\\_/qqbcgd.pdf](http://profiles.nlm.nih.gov/qq/B/C/G/D/_/qqbcgd.pdf).

<sup>16</sup> Official Journal C 076 , 23/03/1987, p. 0022.

<sup>17</sup> Official Journal C 096 , 17/04/1989, p. 0165.

human cloning and the framework decisions for bidding research involving reproductive cloning<sup>18</sup>.

### 3.2. Biometrics and 'dual use' technology

A preliminary overview of soft law instruments which address biometrics and 'dual use' technologies indicate that they take mainly the form of Communications and Recommendations by the European Commission. In this field soft law covers also a broad range of instruments from Opinions of the Economic and Social Committee and the European Data Protection Supervisor, to Commission Staff Working Documents, most of them related generally to the 'Area of Freedom, Security and Justice', immigration policies and border security.

Biometrics constitutes a peculiar example of the development of soft law instruments and the way they interconnect with hard law ones. Particularly concerning biometrical data protection, Directive 95/46/EC of the European Parliament and of the Council of 24th October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data<sup>19</sup> remits in Article 27, 1 to self-regulation by stating that 'The Member States and the Commission shall encourage the drawing up of codes of conduct intended to contribute to the proper implementation of the national provisions adopted by the Member States pursuant to this Directive, taking account of the specific features of the various sectors'. This article thus combines features of hard law, soft law and self-regulation.

Similarly, with respect to dual use technologies soft law instruments consist frequently of communications from the Commission about military aspects, and rules governing the exports of military technology, e.g. the 'European Union Code of Conduct on Arms Export', the 'Communication on the EU Counter-Terrorism Policy: main achievements and future challenges' (EC 2010d) and the 'Communication on Conflict Prevention' (EC 2001c). The Green Paper on Bio-preparedness, addressing biological risks and security and safety in the biological/biotechnological area, proposes explicitly the creation of a European Bio-Network with the role to 'to recommend possible guidelines and codes of conduct for researchers concerning materials and resources for education about effective and secure bio-standards

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<sup>18</sup> Decision 1982/2006/EC, of 18 December 2006, 7<sup>th</sup> framework programme, Article 6; Decision 1513/2002/EC, of 27 June 2002, 6<sup>th</sup> Framework Programme, Annex I; and Decision 2002/834/EC, of 30 September 2002, Annex I.

<sup>19</sup> Applicable to personal data to be processed in the context of passports and travel documents by Regulation No. 2252/2004 (Article 4).

and best practices' taking into account the rules on export controls for dual-use technologies (EC 2007, 8) adding that 'expert groups of the Biological and Toxin Weapons Convention recommended that codes of conduct should involve all actors dealing with bio issues' (EC 2007, 13). Finally, the Green Paper recommends that 'Compulsory academic courses in life sciences could focus on dual-use consequences of bioresearch and on ethics of bio-research' (EC 2007, 13).

#### 4. The efficacy of soft law in S&T

As pointed out, there are some likely reasons for adopting soft law in S&T. One is the fact that these are more rapidly developing fields where the degree of scientific uncertainty is often high thus requiring more flexible instruments, at least at an initial stage (e.g. in nanosciences and nanotechnologies). Soft law may also offer a way to deal with social uncertainty or controversy in socially sensitive areas, namely when public authorities want to test the reaction of public opinion to a specific subject (Gersen; Posner 2008, 41) (e.g. cloning). The lack of agreement between Member States or the lack of formal EU jurisdiction on some matters can also be more easily bypassed through soft law originating from European institutions (e.g. for dual use technology). In all these cases, soft law may lead to hard law at a later stage if the grounds for its earlier adoption are overcome.

In the form of self-regulation EU institutions in recent times have actively encouraged soft law. In a number of documents, namely, 'Current state of co-regulation and self-regulation in the Single Market', the 'Opinion on better lawmaking' and the 'Opinion on making European citizenship visible and effective', the Economic and Social Committee asserted that 'to develop a more citizen-oriented governance of the Union' 'socio-professional self-regulation and co-regulation in all areas of direct relevance to civil society' should develop whereby the 'socio-professional actors themselves are not only consulted but are actually involved in defining economic or social rules which concern them directly' (EESC 2006b, 163, 168). Yet, the Committee points out that 'In areas that very directly affect health and safety, and more broadly in the case of services of general interest, co-regulation and self-regulation – even if backed up by sanctions – can prove inadequate in the absence of legislative provisions' (EESC 2005, 23). In its resolution of 2007 on the use of soft law, the European Parliament goes farther in its critique of soft law as an exclusive means of regulation, even recognizing that they may produce legal effects.

Indeed, more and more soft law appears to be combined with hard law in complementary or supporting ways.

## 5. Final remarks

Currently there seems to be an inclination of EU institutions to resort to soft law. This tendency may be understood in the light of the EU as a multilevel governance system but while the European Commission or the European Economic and Social Committee encourage it, the European Parliament criticizes what the Parliament considers a somewhat opaque way to illegitimately enlarge EU's jurisdiction.

There are a wide variety of soft law instruments, even wider if we include self-regulation. Self-regulation ranges from technical and professional codes of conduct to sectorial guidelines. Additionally, the separation between soft law as public enacted and self-regulation arising from the private sphere appears to be blurred.

In science and technology, to the extent that soft law features pre-regulatory or bottom-up regulatory action, it may be regarded as a favourable and flexible vehicle to translate ethical, values-related concerns linked to the impacts of science and technology and these are among the main motivations and justifications to resort to soft law in this field. But from the analysis of the different technologies we can detect a tendency to resort to soft law in fields such as biotechnologies, the same does not happen with biometrics for instance.

Does soft law relate more easily to the idea of governance and the perception of societal changes in recent times than hard law? At least, that seems to be the perspective arising from official documents linking soft law, self and co-regulation to a more involved and participative society. That is observed when soft law acts as pre-law, paving the way for hard law instruments. But in the area of science and technology in particular, while soft law may constitute a reply to the rhythm of change and the need to accommodate the societal and ethical dimensions at stake, doubts subsist concerning its effectiveness as a regulatory means.



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